



(51) International Patent Classification 6 : A61B 5/06, 8/08, A61M 25/01, A61B 17/39		(11) International Publication Number: WO 96/05768
A1		(43) International Publication Date: 29 February 1996 (29.02.96)
(21) International Application Number: PCT/US95/01103		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ).
(22) International Filing Date: 24 January 1995 (24.01.95)		
(30) Priority Data: 08/293,859 19 August 1994 (19.08.94) US		
(71) Applicant (for all designated States except US): BIOSENSE, INC. [US/US]; 40 Ramland Road South, Orangeburg, NY 10962 (US).		
(72) Inventors; and (75) Inventors/Applicants (for US only): BEN-HAIM, Shlomo [IL/IL]; 101 Yefe Nof Street, 34454 Haifa (IL). OSADCHY, Daniel [IL/IL]; 48A Harofe Street, 34367 Haifa (IL). PELESS, Udi [IL/IL]; P.O. Box 420, 4500 Evan Yehuda (IL). GREENBERG, Ilan [IL/IL]; 15 Geula Street, 33198 Haifa (IL).		
(74) Agents: DIPPERT, William, H. et al.; Cowan, Liebowitz & Latman, P.C., 1133 Avenue of the Americas, New York, NY 10036-6799 (US).		

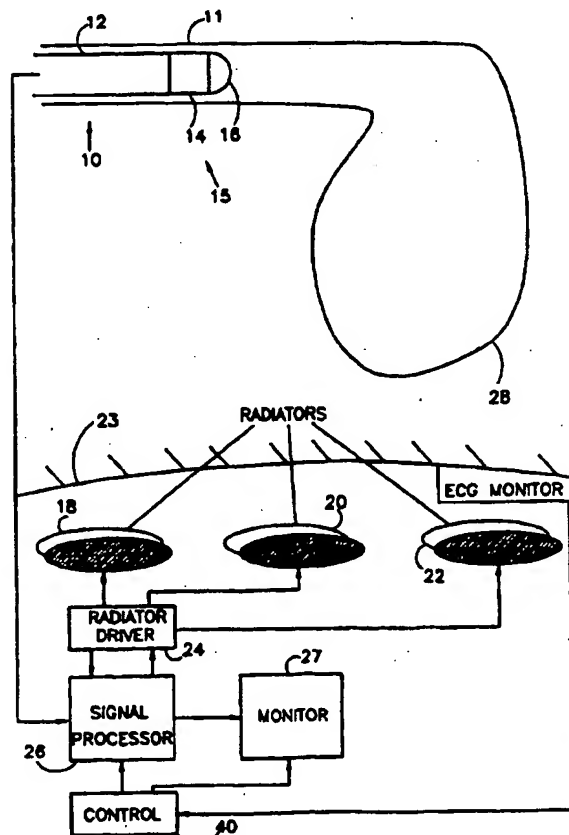
Published

With international search report.

(54) Title: MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS

(57) Abstract

A locating system for determining the location and orientation of an invasive medical instrument, for example a catheter (10) or endoscope, relative to a reference frame, comprising: a plurality of field generators (18, 20, 22) which generate known, distinguishable fields, preferably continuous AC magnetic fields, in response to drive signals; a plurality of sensors (30, 32, 34) situated in the invasive medical instrument (10) proximate the distal end thereof which generate sensor signals in response to said fields; and a signal processor (26) which has an input for a plurality of signals corresponding to said drive signals and said sensor signals and which produces the three location coordinates and three orientation coordinates of a point on the invasive medical instrument.



BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

1 MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS

2 FIELD OF THE INVENTION

3 The present invention relates to medical diagnosis,
4 treatment and imaging systems. More particularly, the
5 present invention relates to medical probes whose location
6 can be detected and adjusted and which have an additional
7 detection, imaging and/or treatment function.

8 BACKGROUND OF THE INVENTION

9 Probes, such as catheters, suitable for various medical
10 procedures and internal imaging, are fairly common. Such
11 probes include: balloon angioplasty catheters, catheters
12 with laser-, electrical- or cryo-ablation characteristics,
13 catheters having ultrasound imaging heads, probes used for
14 nearly incisionless-surgery or diagnosis, and endoscopes.
15 Where such probes are used for treatment, the probes must be
16 carefully positioned in relation to the body structure. Even
17 for imaging systems such as ultrasound systems, some
18 positioning capability has been described.

19 In cardiovascular examinations and in particular in
20 those using invasive techniques, multiple catheters are
21 inserted into the vascular system and then advanced towards
22 the cardiac chambers. The procedure itself is generally
23 performed under fluoroscope guidance which necessitates the
24 use of a continuous source of x-ray as a transillumination
25 source. The image generated using the fluoroscope is a 2D
26 display of the anatomy with the location of the catheter
27 superimposed. The anatomy can be viewed with a relatively
28 low resolution since the cardiac chamber and the blood
29 vessels are transparent to the x-ray radiation.

30 More recently, several technologies have been developed
31 to ease the process of cardiac catheterization, mainly by
32 enabling the physician to follow the path of the tip of the
33 catheter inside the blood vessel. Some of this technology
34 is based on digital subtraction radiography technology that
35 enables viewing the blood vessel after the injection of a
36 radio contrast dye and superimposing on that image the path

1 of the catheter. These technologies necessitate the use of
2 radiopaque dyes which are a major cause of morbidity in
3 high-risk patients during cardiac catheterization.

4 U.S. Patent No. 5,042,486 to Pfeiller et al., the
5 disclosure of which is incorporated herein by reference,
6 describes a method in which the position of a catheter tip
7 is located using electromagnetic fields. The catheter is
8 introduced and the tip location is followed. The path of
9 the tip is superimposed on the pre-registered image of the
10 blood vessel or the organ, through which the catheter was
11 advanced. However, this technology requires acquisition and
12 processing of images prior to the procedure and involves a
13 highly sophisticated and time-consuming procedure for the
14 correct alignment of the image acquired previous to this
15 procedure, and the orientation and location of the blood
16 vessel or the organ during the catheterization procedure
17 itself.

18 U.S. Patent 4,821,731 to Martinelli et al., the
19 disclosure of which is incorporated herein by reference,
20 discloses a method for internal imaging of a living body
21 using ultrasound. In this patent the position of an
22 ultrasound imaging catheter is determined by computing the
23 relative position of the catheter using the response of an
24 ultrasound transducer to a reference signal and by computing
25 the angular orientation of the catheter about its axis by
26 determining the signal induced in a single coil by
27 substantially perpendicular magnetic fields of different
28 frequencies. The ultrasound transducer is also used to send
29 and detect ultrasound signals in a direction perpendicular
30 to the catheter axis. By rotating the catheter and moving it
31 along its axis an ultrasound image may be generated. The
32 catheter is also described as being capable of transmitting
33 a laser beam to the end thereof to ablate tissue from
34 lesions on the walls of arteries.

35 A catheter which can be located in a patient using an
36 ultrasound transmitter located in the catheter, is disclosed

1 in U.S. Patent No. 4,697,595 and in the technical note
2 "Ultrasonically Marked Catheter, a Method for Positive
3 Echographic Catheter Position and Identification", Bryer et
4 al., Medical and Biological Engineering and Computing, May,
5 1985, pages 268-271. Also, U.S. Patent No. 5,042,486
6 discloses a catheter which can be located in patients using
7 non-ionizing fields and suitably imposing catheter location
8 on a previously obtained radiological image of the blood
9 vessel.

10 PCT Patent Publication WO 94/0938, the disclosure of
11 which is incorporated herein by reference, describes a
12 system using a single-coil type sensor which is coaxial with
13 the long axis of a catheter and which senses fields which
14 are generated by three multicoil generators external to the
15 body of a patient.

16 Other methods and apparatus for the determination of
17 the position of a catheter or endoscope are shown in U.S.
18 Patents 5,253,647; 5,057,095; 4,095,698; 5,318,025;
19 5,271,400; 5,211,165; 5,265,610; 5,255,680; 5,251,635 and
20 5,265,611.

21 U.S. Patent No. 3,644,825 describes a system which uses
22 the relative motion of a sensor in the determination of its
23 position. The relative motion supplies information to the
24 sensing coils needed to identify position and orientation.
25 However, such a solution is not applicable to identifying
26 position and location of the object where there is no
27 relative motion between the object and the reference frame.

28 U.S. Patent No. 3,868,565, the disclosure of which is
29 incorporated herein by reference, comprises a tracking
30 system for continuously determining the relative position
31 and orientation of a remote object. This tracking system
32 includes orthogonally positioned loops for both a plurality
33 of sensors and a plurality of radiating antennas. With the
34 proper excitation currents to those loops, the radiating
35 antennas generate an electromagnetic field that is radiated
36 from those antennas to the sensor. The tracking system

1 operates as a closed loop system where a controlling means
2 measures the field that is received at the sensor at the
3 remote object and feeds the information back to radiating
4 antennas to provide a nutating field radiating as a pointing
5 vector towards the remote object. Accordingly, the pointing
6 vector gives the direction to the sensing antenna from the
7 radiating antenna.

8 Similarly, Kuipers describes in his U.S. Patent No.
9 4,017,858, the disclosure of which is incorporated herein by
10 reference, an electromagnetic field which rotates about a
11 pointing vector and is used both to track or locate the
12 remote object in addition to determining the relative
13 orientation of the object. This system, wherein the
14 radiating coils are charged with the properly designed wave
15 forms, generates a magnetic field which, in a closed loop
16 manner, can be fed into processing means to generate the
17 information needed to determine an orientation of a remote
18 object.

19 U.S. Patent No. 4,054,881, the disclosure of which is
20 incorporated herein by reference, describes a non-tracking
21 system for determining the position and location of a remote
22 object with respect to a reference frame. This is
23 accomplished by applying electrical signals to each of three
24 mutually-orthogonal, radiating antennas, the electrical
25 signals being multiplexed with respect to each other and
26 containing information characterizing the polarity and
27 magnetic moment of the radiated electromagnetic fields. The
28 radiated fields are detected and measured by the three
29 mutually orthogonal receiving antennas having a known
30 relationship to the remote object, which produce nine
31 parameters. These nine parameters, in combination with one
32 known position or orientation parameter, are sufficient to
33 determine the position and orientation parameters of the
34 receiving antennas with respect to the position and
35 orientation of the radiating antennas.

36 U.S. Patent No. 4,849,692, the disclosure of which is

1 incorporated herein by reference, describes a quantitative
2 method for measuring the relative position and orientation
3 of two bodies in the presence of metals. Measuring the
4 position and orientation of receiving antennas with respect
5 to the transmitting antennas is achieved using direct
6 current electromagnetic field signals. Electromagnetic
7 radiation is designed to be transmitted in a sequence by
8 each of the mutually orthogonal radiating antennas. A
9 receiving antenna measures the values of transmitted direct
10 current magnetic fields, one dimension at a time, and those
11 of the earth's magnetic field as well. This method requires
12 repetitive acquisition and computations to determine
13 position and location of remote objects.

14 Other methods which are known in the art for
15 determining multi-dimensional positioning and orientation
16 for aircraft and for helmets are described in U.S. Patent
17 4,849,692, European patent publication 0 576 187 A1, GB
18 patent publication 2 197 078 A and U.S. Patent 4,314,251 the
19 disclosures of which are incorporated herein by
20 reference.

21 The above described prior art which is for use in non-
22 medical applications, utilizes sensors and other structures
23 which are not suitable for use in catheters. Those
24 references which are described as being useful for medical
25 probes generally give less than six dimensional information
26 (three position coordinates and three angular coordinates).

27 In previous, as yet unpublished applications assigned
28 to the assignee of the present application, U.S. Patent
29 Application Number 08/094,539, filed July 20, 1993 and PCT
30 Application PCT/US94/08352 filed July 20, 1994, the
31 disclosures of which are incorporated herein by reference, a
32 system is disclosed which incorporates a catheter which
33 includes a position measuring device which can determine the
34 position of the catheter in three dimensions, but not its
35 orientation. In these applications, this catheter is used to
36 map the electrical activity at the inner walls of the heart

1 and to ablate portions of the heart muscle in response to
2 such mappings. The position of the catheter used for the
3 mapping/ablation function is determined with reference to
4 three position detecting devices which are positioned
5 against the inner wall of the heart at three different
6 stable locations to form a reference plane.

7 **SUMMARY OF THE INVENTION**

8 In general the present application discloses a catheter
9 locating means and method that offers quantitative, high
10 resolution locating information that, when assimilated with
11 sensed local information results in a high resolution,
12 detailed map of the information. This map may optionally be
13 superimposed on an image or other representation of the
14 organ architecture.

15 The locating means preferably generates continuous
16 location and orientation information concerning a remote
17 object, in particular a catheter, relative to a reference
18 frame, in a non-iterative manner.

19 One aspect of the present invention relates to the
20 provision of a new six-dimensional positioning apparatus
21 suitable for use with a catheter.

22 In a preferred embodiment of this system, a plurality
23 of non-concentric coils are placed in a catheter adjacent a
24 locatable site, for example, its distal end. The coils
25 preferably have orthogonal axis. The relative positioning of
26 the coils differs from that described in the prior art in
27 that the coils are separated in space and are not
28 concentric. These coils generate signals in response to
29 externally applied magnetic fields which allows for the
30 computation of six position and orientation dimensions.

31 A second aspect of the present invention is directed
32 toward a new method for computing multi-dimensional position
33 and orientation of a coil system from signals produced by
34 the coils in response to a system of externally applied
35 electromagnetic fields.

36 A third aspect of the present invention allows for the

1 mapping of the interior of the heart in a manner similar to
2 that described in the above-referenced patent applications
3 assigned to the assignee of the present application, with
4 the simplification that only a single six-dimensional
5 location/orientation detection sensor is used for reference.

6 A fourth aspect of the present invention involves an
7 ultrasonic or other imaging probe having a six-dimensional
8 positioning capability in response to external
9 electromagnetic fields. Use of such a probe obviates the use
10 of ionizing radiation or sonic sensing for position
11 determination and gives ultrasonic or other imaging
12 information whose direction and orientation is completely
13 known.

14 A fifth aspect of the invention involves methods and
15 apparatus for adding a controlled change in orientation to a
16 catheter, thereby to allow for maneuvering of the cathode
17 and its easy placement.

18 A sixth aspect of the invention utilizes the controlled
19 change in orientation to allow for two or three-dimensional
20 imaging using a non-scanning probe, such as an ultrasound
21 probe or for three-dimensional scanning using a two-
22 dimensional scanning probe.

23 There is therefore provided, in accordance with a
24 preferred embodiment of the invention, a locating system for
25 determining the location and orientation of an invasive
26 medical instrument, for example a catheter or endoscope,
27 relative to a reference frame, comprising:

28 a plurality of field generators which generate known,
29 distinguishable fields, preferably continuous AC magnetic
30 fields, in response to drive signals;

31 a plurality of sensors situated in the invasive medical
32 instrument proximate the distal end thereof which generate
33 sensor signals in response to said fields; and

34 a signal processor which has an input for a plurality
35 of signals corresponding to said drive signals and said
36 sensor signals and which produces the three location

1 coordinates and three orientation coordinates of a point on
2 the invasive medical instrument.

3 Preferably one or both of the plurality of field
4 generators or sensors comprises three distinguishable, non-
5 overlapping, generators or sensors.

6 In a preferred embodiment of the invention, each sensor
7 comprises a coil. Preferably, said plurality of coils have
8 axes which intersect within a coil. When said plurality of
9 coils comprises three coils, said coils preferably have axes
10 which do not all intersect in a point.

11 Preferably, the signal processor cross-correlates the
12 signals corresponding to the drive and sensor signals.

13 Preferably, the fields generated by each of the
14 generators have a different frequency, a different phase, or
15 both a different frequency and a different phase.

16 In a preferred embodiment of the invention the field
17 generated by each field generator has a different frequency,
18 preferably frequencies which are each integer multiples of a
19 given frequency. Preferably, the duration of the cross-
20 correlation of the inputs is the minimal common product of
21 the integer multipliers divided by the given frequency.

22 Preferably, the results of the cross-correlation are
23 used to calculate the contribution of each field generator
24 to the signal generated by each said sensor.

25 In a preferred embodiment of the invention the locating
26 system includes a display system for displaying the position
27 of the point on the invasive medical instrument.

28 Preferably, the locating system further comprises a
29 reference instrument which includes a plurality of non-
30 overlapping sensors situated in the reference instrument
31 which sensors generate sensor signals in response to said
32 fields, wherein said display system displays the position of
33 the point on the invasive medical instrument relative to the
34 position of a point on the reference instrument. Preferably
35 the reference instrument is an invasive medical instrument.
36 Preferably, the sensors are situated proximate the distal

1 end of the reference invasive medical instrument.

2 In a preferred embodiment of the invention the locating
3 system includes an additional sensor on a portion of the
4 invasive medical instrument which senses a local condition.

5 Preferably, the additional sensor senses local
6 electrical signals, for example electrical signals from the
7 endocardium of the patient's heart, and transfers them to
8 terminals external to the patient's body.

9 In a preferred embodiment of the invention the signal
10 processor processes the position and orientation coordinate
11 signals and the local electrical signals acquired at a
12 plurality of points on the endocardium to generate a map
13 that represents the propagation of electrical signals
14 through tissue in the patient's body.

15 In a preferred embodiment of the invention the
16 additional sensor supplies electrical energy to the
17 endocardium for ablating a portion of the endocardium.

18 Preferably the locating system includes an electrode
19 adapted for supplying electrical energy to the endocardium
20 for ablating a portion of the endocardium.

21 In a preferred embodiment of the invention the
22 additional sensor is an ultrasonic transmitter/receiver.

23 Preferably, the ultrasonic transmitter/receiver
24 provides a less than three dimensional representation of the
25 acoustic properties of tissue beyond the distal end.

26 In a preferred embodiment of the invention, the distal
27 end is deflectable. Preferably, the system includes image
28 reconstruction circuitry which receives a plurality of said
29 less than three dimensional representations acquired at
30 different orientations of the distal end and produces a
31 three dimensional map of the acoustic properties of tissue
32 at least partially surrounding the distal end.

33 There is further provided, in accordance with a
34 preferred embodiment of the invention, an imaging system for
35 intrabody ultrasonic imaging comprising:

36 a invasive medical instrument, preferably, a catheter

1 or endoscope, having an axial-looking ultrasonic imaging
2 transducer at the distal end thereof which generated a
3 representation, preferably a one or two dimensional
4 representation, of the acoustic properties of tissue beyond
5 the distal end;

6 means for manipulating the distal end to change the
7 orientation thereof; and

8 image reconstruction circuitry which receives a
9 plurality of said representations acquired at different
10 orientations of the distal end and produces a three
11 dimensional map of the acoustic properties of tissue at
12 least partially surrounding the distal end from said
13 plurality of representations.

14 Preferably, the imaging system further comprises:

15 a plurality of field generators which generate known,
16 distinguishable fields in response to drive signals;

17 a plurality of sensors situated in the invasive medical
18 instrument proximate the distal end thereof which generate
19 sensor signals in response to said fields; and

20 a signal processor which has an input for a plurality
21 of signals corresponding to said drive signals and said
22 sensor signals and which produces three location coordinates
23 and three orientation coordinates of the a point on the
24 transducer.

25 There is further provided a method of determining the
26 position and orientation of an invasive medical instrument,
27 for example a catheter or endoscope, having a distal end,
28 comprising:

29 (a) generating a plurality, preferably three, of
30 distinguishable, geometrically different AC magnetic
31 fields;

32 (b) sensing the AC magnetic fields at the sensors at a
33 plurality of points proximate the distal end; and

34 (c) computing six dimensions of position and
35 orientation of a portion of the invasive medical instrument
36 responsive to signals representative of the generated

1 magnetic fields and the sensed magnetic fields.

2 Preferably, the AC magnetic field is sensed at three
3 points of the invasive medical instrument.

4 There is further provided, in accordance with a
5 preferred embodiment of the invention, an ultrasonic intra-
6 body imaging method comprising:

7 (a) inserting an ultrasonic transducer into the body,
8 said ultrasonic transducer producing a representation of the
9 acoustic properties of tissue beyond an end of the
10 transducer;

11 (b) manipulating the orientation of the transducer to
12 provide a plurality of said representations; and

13 (c) constructing a three dimensional map of the
14 acoustic properties of the tissue in a region at least
15 partially surrounding the end of the transducer from said
16 plurality of representations.

17 Preferably, the method includes determining the six
18 dimensions of position and orientation of the transducer for
19 each of the representations.

20 Preferably, the representation is a less than three
21 dimensional representation.

22 There is further provided an invasive medical
23 instrument, for example a catheter or endoscope, comprising
24 a plurality of magnetic field sensors, preferably coils,
25 proximate the distal end thereof.

26 Preferably the plurality of coils have axes which
27 intersect within a coil. Where the plurality is three, the
28 said coils have axes which do not all intersect in a point.

29 In a preferred embodiment of the invention, the
30 instrument comprises an ultrasound transducer at said distal
31 end. Preferably, the ultrasound transducer provides a
32 representation, preferably a one or two dimensional
33 representation, of the acoustic properties of tissue beyond
34 and along the axis of the catheter.

35 In a preferred embodiment of the invention, the
36 instrument further comprises an electrical probe at said

1 distal end. The probe is preferably adapted to sense
2 electrical signals generated by tissue which is in contact
3 and conduct said signals to the proximal end of the catheter
4 and/or to supply an ablative electrical signal to tissue
5 contacting said terminal. In a preferred embodiment of the
6 invention, the instrument includes a sensor for measuring
7 local chemistry at the distal end.

8 Preferably, the instrument includes means for changing
9 the orientation of the distal end.

10 There is further provided, in accordance with a
11 preferred embodiment of the invention, apparatus for
12 steering the distal end of an invasive medical instrument,
13 such as a catheter or endoscope, comprising:

14 a relatively more flexible wire passing through the
15 catheter that is attached to the distal end and has a bend
16 near the distal end;

17 a relatively more rigid sleeve which is straight near
18 the distal end and which slideably holds the wire thereat,
19 whereby when the sleeve is slid over the wire, the wire and
20 distal end are straightened.

21 Preferably, the instrument has a lengthwise axis and
22 the wire is sited off the axis of the instrument.

23 There is further provided apparatus for steering the
24 distal end of an invasive medical instrument comprising:

25 a flat relatively flexible portion being slit along a
26 portion of the length thereof to form two portions which are
27 attached at a first end thereof, said first end being
28 attached to the distal end of the instrument;

29 a pair of wires, one end of each of which being
30 attached to one of said portions at a second end thereof;
31 and

32 means for changing the relative lengths of the wires
33 whereby the flexible element is bent, thereby steering the
34 distal end of the instrument.

35 There is further provided, in accordance with a
36 preferred embodiment of the invention, a method of producing

1 a three dimensional image of the internal surface of an
2 internal body organ comprising:

3 measuring the distance to said surface at a plurality
4 of orientations from within the internal surface; and
5 assembling the distances to form an image of the
6 surface.

7 Preferably, the measurement of distances is made from a
8 plurality of points within the organ. Preferably, the
9 measurement of distances is preformed utilizing an
10 ultrasonic transducer.

11 BRIEF DESCRIPTION OF THE DRAWINGS

12 Fig. 1 is a pictorial representation of the application
13 of a system for six-dimensional position and bearing
14 determination, in accordance with a preferred embodiment of
15 the invention to a catheter located in a human body;

16 Fig. 2 is a schematic, cut-away illustration of a
17 generalized catheter having a six-dimensional location
18 capability in accordance with a preferred embodiment of the
19 present invention;

20 Fig. 3 is a more graphic illustration of a portion of
21 the probe showing a preferred embodiment of a sensor for
22 six-dimensional location;

23 Fig. 4 is a block diagram of circuitry used to
24 determine the six-dimensional coordinates of a catheter, in
25 accordance with a preferred embodiment of the invention;

26 Fig. 5 shows in expanded detail the basic flow chart
27 representing a control sequence and its application to the
28 block diagram of Fig. 4, in accordance with a preferred
29 embodiment of the invention;

30 Fig. 6 is a block diagram representing digital signal
31 processing in the signal processor in accordance with a
32 preferred embodiment of the invention;

33 Fig. 7 is a three-dimensional graphic representation of
34 the vectors forming the magnetic field at a point;

35 Fig. 8 is a block diagram representing analog signal
36 processing in the signal processor, in accordance with a

1 preferred embodiment of the invention;

2 Fig. 9 is a simplified schematic of an analog filter
3 element shown in Fig. 8, in accordance with a preferred
4 embodiment of the invention;

5 Figs. 10A-10D illustrate a principle of orienting the
6 tip of a catheter in accordance with a first preferred
7 embodiment of the invention;

8 Fig. 11 illustrates a principle of orienting the tip of
9 a catheter in accordance with a second preferred embodiment
10 of the invention;

11 Fig. 12 is a block diagram of ultrasonic acquisition
12 and signal processing circuitry in accordance with a
13 preferred embodiment of the invention;

14 Fig. 13 is a block diagram of image reconstruction
15 circuitry in accordance with a preferred embodiment of the
16 invention;

17 Fig. 14 is a partially schematic, partially cut-away
18 illustration of a probe for electrical sensing, pacing and
19 ablation in accordance with a preferred embodiment of the
20 invention;

21 Fig. 15 is a schematic block diagram for acquiring a
22 basic electrogram map in accordance with a preferred
23 embodiment of the present invention;

24 Fig. 16 is a schematic block diagram representing a
25 computerized endocardial mapping algorithm, in accordance
26 with a preferred embodiment of the invention;

27 Fig. 17 is a schematic block diagram representing a
28 computerized pace mapping algorithm, in accordance with a
29 preferred embodiment of the invention;

30 Fig. 18 is a schematic block diagram of an algorithm
31 used to calculate the cross-correlation index while pace-
32 mapping, in accordance with a preferred embodiment of the
33 invention; and

34 Fig. 19 is a schematic block diagram representing an
35 output configuration of an imaging system in accordance with
36 a preferred embodiment of the invention.

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 Figure 1 shows a pictorial representation of a basic
3 preferred application of the invention to the human body. In
4 this application, a catheter 10 is inserted into an artery
5 11 of a patient using standard techniques. Catheter 10
6 comprises a body 12, a locating sensor 14 and an active
7 portion 16 at the distal end 15 of the catheter. The active
8 portion 16, in accordance with various preferred embodiments
9 of the invention, may include an electrical sensor, an
10 ultrasound head, a fiber optic viewing head, an electrical
11 stimulator, an electrical or laser ablator, an ionic sensor,
12 an oxygen or carbon dioxide sensor, an accelerometer, a
13 blood pressure or temperature sensor or a cryogenic probe.
14 In general the catheter will include leads, light guides,
15 wave guides, etc. for energizing the active portion in
16 response to commands of an operator.

17 The position and orientation of the distal end of the
18 catheter is ascertained by determining the position of the
19 locating sensor. In a preferred embodiment of the invention,
20 the locating sensor comprises two or three antennas, for
21 example coils which are irradiated by two or three radiators
22 18, 20 and 22, which are outside the body surface 23 of the
23 patient.

24 It should be understood that placement of the
25 radiators, as well as their size and shape, will vary
26 according to the application of the invention. Preferably
27 the radiators useful in a medical application comprise wound
28 annular coils from about 2 to 20 cm in diameter (O.D.) and
29 from about 0.5 to 2 cm thick, in a coplanar, triangular
30 arrangement where the centers of the coils are from about 2
31 to 30 cm apart. Bar-shaped radiators or even triangular or
32 square-shaped coils could also be useful for such medical
33 applications. Moreover, in instances where a prone patient
34 will be the subject of a procedure involving the instant
35 technology, the radiators are preferably positioned in or
36 below the surface upon which the patient is resting,

1 substantially directly below the portion of the patient's
2 body where a procedure is being performed. In other
3 applications, the radiators may be fairly close to the skin
4 of the patient.

5 The three radiators are driven by a radiator driver
6 24, preferably in a manner described below, and the signals
7 received by the receiving antennas are amplified and
8 processed, together with a representation of the signals
9 used to drive radiators 18, 20 and 22, preferably in the
10 manner described below, in a signal processor 26 to provide
11 a display or other indication of the position and
12 orientation of the distal end 15 on a monitor 27.

13 Radiators 18, 20 and 22 may be arranged in any
14 convenient position and orientation, so long as they are
15 fixed in respect to some reference frame, and so long as the
16 radiators are non-overlapping; that is, there are no two
17 radiators with the exact, identical location and
18 orientation. When driven by radiator driver 24, the
19 radiators generate a multiplicity of distinguishable AC
20 magnetic fields that form the magnetic field sensed by
21 receiving antennas in the locating sensor.

22 The magnetic fields are distinguishable with regard to
23 the frequency, phase, or both frequency and phase of the
24 signals in the respective magnetic fields. Time multiplexing
25 is also possible.

26 In practice the active end of the catheter may be used
27 to gather information, such as ultrasound echo information,
28 electrical activity information etc., and optionally to
29 perform certain procedures on the arteries (or veins) or
30 within an organ chamber 28 to which the artery (or vein)
31 leads. Particular examples of organ chambers are the
32 chambers of the heart, brain or gastrointestinal tract. It
33 is a particular object of some aspects of the present
34 invention to more accurately map the electrical activity of
35 the heart and to more accurately image the walls of the
36 heart, as will be described in more detail below.

1 Fig. 2 shows a schematic illustration of a preferred
2 embodiment of the distal end of catheter 10. A graphic
3 illustration of locating sensor 14 is shown in Fig. 3.
4 Sensor 14 preferably includes two or more and more
5 preferably three sensor coils 30, 32 and 34 wound on air
6 cores. In a preferred embodiment of the invention the coils
7 have mutually orthogonal axes, one of which is conveniently
8 aligned with the long axis of the catheter. Unlike prior art
9 location sensors (used for other applications) which contain
10 three coils that are concentrically located, or at least
11 whose axes intercept, the coils of the preferred embodiment
12 of the invention are closely spaced along the axis of the
13 catheter to reduce the diameter of the locating sensor and
14 thus make the sensor suitable for incorporation into a
15 catheter.

16 For most aspects of the present invention, quantitative
17 measurement of the position and orientation of the catheter
18 distal end relative to a reference frame is necessary. This
19 requires at least two non-overlapping radiators that
20 generate at least two distinguishable AC magnetic fields,
21 the radiators' respective positions and orientations
22 relative to the reference frame being known; a radiator
23 driver which preferably continuously supplies the radiators
24 with AC signals to generate the AC magnetic fields; and a
25 location sensor, consisting of at least two non-parallel
26 sensors to measure the magnetic field flux resulting from
27 the at least two distinguishable magnetic fields. The
28 number of radiators times the number of sensors is equal to
29 or greater than the number of degrees of freedom of the
30 desired quantitative measurement of the position and
31 orientation of the sensors relative to the reference frame.

32 Since, in a preferred embodiment of the invention it is
33 preferred to determine the six position and orientation
34 coordinates of the distal tip of the catheter, at least two
35 coils are required in location sensor 14. Preferably three
36 coils are used to improve the accuracy and reliability of

1 the position measurement. In some applications where fewer
2 dimensions are required, only a single coil may be necessary
3 in locating sensor 14.

4 Leads 36 are used to carry signals detected by the
5 sensor coils to signal processor, via the proximal end of
6 the catheter, for processing to generate the required
7 position information. Preferably, leads 36 are twisted pairs
8 to reduce pick-up and may be further electrically shielded.

9 In a preferred embodiment of the invention, coils 30,
10 32 and 34 have an inner diameter of 0.5 mm and have 800
11 turns of 16 micrometer diameter to give an overall coil
12 diameter of 1-1.2 mm. The effective capture area of the coil
13 is preferably about 400 mm². It will be understood that
14 these dimensions may vary over a considerable range and are
15 only representative of a preferred range of dimensions. In
16 particular, the size of the coils could be as small as 0.3
17 mm (with some loss of sensitivity) and as large as 2 or
18 more mm. The wire size can range from 10-31 micrometers and
19 the number of turns between 300 and 2600, depending on the
20 maximum allowable size and the wire diameter. The effective
21 capture area should be made as large as feasible, consistent
22 with the overall size requirements. While the preferred
23 sensor coil shape is cylindrical, other shapes can also be
24 used. For example a barrel shaped coil can have more turns
25 than a cylindrical shaped coil for the same diameter of
26 catheter. Also, square or other shaped coils may be useful
27 depending on the geometry of the catheter.

28 Leads 38 are used to power active portion 16 and/or to
29 receive signals therefrom. The nature of leads 38, which may
30 vary and may, for example, include an optical waveguide or
31 other transmission media as appropriate to their task.

32 For example, an electrode located on the distal tip of
33 the catheter records local cardiac electrical activity, for
34 example, on the endocardium. These local electrograms
35 (ECG's) are transferred via leads 38 to the proximal end of
36 the catheter and fed into an ECG amplifier. The amplified

1 ECG signals are transferred to the control system that
2 presents to the physician the local electrogram morphology
3 acquired from the site whose location was determined at the
4 same time.

5 Figure 4 is a block diagram of preferred circuitry used
6 in computing the position of locating sensor 14. In this
7 exemplary embodiment, three radiators 18, 20 and 22 and
8 three sensor coils 30, 32 and 34 are used. Radiator driver
9 24 provides distinguishable, simultaneous AC current signals
10 to each radiator. Control circuitry 40 utilizes D/A
11 convertors 42, 44 and 46 to generate three sine waves of
12 three different frequencies, f_1 , f_2 and f_3 , which are output
13 separately to signal amplifiers 48, 50 and 52.

14 In order to achieve a fast response locating system the
15 use of slow responding filters has been eliminated by using
16 cross-correlation of the radiated and the received signals.
17 This cross-correlation is performed over a window in time
18 which contains an integer number of the cycle lengths of the
19 three radiated signals. Use of an integer number of cycles
20 generally results in a decrease in processing errors and a
21 more accurate determination of the relative amplitude and
22 phase of the signals received by the sensor coils. If non-
23 integral cycle lengths are used an error in the cross-
24 correlation generally results, unless a very long
25 correlation window is used.

26 If a short correlation window is used, (the shortest is
27 the minimal common product of the cycle times), the ratio
28 between frequencies should be a rational number. The
29 frequency of a radiator c , f_c , where $c = 1, 2$ or 3 should
30 satisfy the equation:

$$31 \quad f_c = n_c \cdot f_b \quad (1)$$

32 where n_c is any positive integer such that $n_1 \neq n_2$, $n_2 \neq n_3$,
33 and $n_3 \neq n_1$, and f_b is an arbitrary base frequency to assure
34 that integral cycle lengths can be used for cross-
35 correlation.

36 The radiating driver amplifier output signals are

1 delivered to the radiators through current sensitive
2 circuitry 54, 56 and 58, such as a resistor, loop or more
3 sophisticated circuitry as is known in the art. The current-
4 sensitive circuitry produces an output which represents the
5 amplitude and phase of the driving signal for the radiators
6 and which is passed to signal processor 26. With this
7 arrangement, the three radiators will generate a magnetic
8 field composed of three differently oriented field
9 components each having a different known frequency. Each of
10 these field components will be sensed by each of sensor
11 coils 30, 32 and 34 which will each produce a signal
12 composed of three frequency components having different
13 amplitudes and phases depending on the relative distance and
14 orientation of the particular sensor coil and particular
15 radiator which radiates a particular frequency.

16 The outputs signals of sensors 30, 32 and 34 are
17 amplified in amplifiers 60, 62 and 64 respectively and
18 passed on to signal processor 26.

19 Fig. 5 shows in expanded detail the basic flow chart
20 representing a control sequence and its application to the
21 circuitry of Fig. 4. During the initialization phase,
22 indicated by block 66, the frequencies of the three sine
23 waves, the physical position and orientation of radiators
24 18, 20 and 22 in respect to a reference frame, the
25 properties of the radiators and sensors and the coordinates
26 of a single point in the mapping field are defined. Sine
27 waves having respective frequencies f_1 , f_2 and f_3 are
28 synthesized as indicated by block 68, for example in control
29 40. These generated frequencies are transmitted, preferably
30 continuously, by radiators 18, 20 and 22 as indicated by
31 block 70 and as described above with reference to Fig. 4.
32 The control sequence enters a timing loop 72 that
33 periodically sends signals to activate the signal processor
34 to cross-correlate the coil sensor signals with the radiated
35 signals and to calculate the orientation and position of
36 locating sensor 14 relative to the reference frame.

1 Both analog and digital embodiments of signal
2 processing are possible in accordance with preferred
3 embodiments of the invention. These different approaches can
4 be modified in a variety of ways by those skilled in the
5 art, and can be combined in different modes in order to
6 practice them simultaneously. Some applications of the
7 present invention would benefit from the digital approach,
8 while the analog approach may be the preferable solution in
9 other cases.

10 The digital embodiment is described in conjunction with
11 Fig. 6, which is a functional block diagram of signal
12 processor 26. The inputs to the processing block are the
13 signals from amplifiers 60, 62 and 64 (the sensor coil
14 signals) denoted by SIG and inputs from current sensing
15 circuits 52, 56 and 58 denoted as CUR. In this embodiment
16 the six input signals are converted from analog to digital
17 signals by an array of A/D converters 74. The sampled
18 digital signals are passed to the "calculate cross
19 correlation" block 76, which may consist of dedicated
20 circuitry or which may be performed by a dedicated or shared
21 microprocessor. Using the six data streams (three AC
22 currents flowing through the radiators and three sensor
23 readings) the cross correlation elements can be calculated
24 using the following method:

25

26 Given that

27 SIG_s is the amplified output of sensor s , where $s = 1,$
28 2 or 3 ;

29 CUR_c is the current flowing through radiator c , where
30 $c = 1, 2$ or 3 ;

31 f_b is an arbitrary base frequency;

32 f_0 is the sampling frequency which is an integral
33 multiple of f_b ; and

34 and N is the correlation length in number of samples,

35 $N = K(f_0/f_b)$, where K is any positive integer,

36 the correlation between CUR_c and the sine wave of frequency

1 f_C is:

2

$$3 \quad A_C^I = (2/N) \cdot \sum CUR_C[i] \cdot \sin(2\pi f_C(i/f_0)); \quad (3)$$

4

5 and the correlation between CUR_C and the cosine wave of
6 frequency f_C is:

7

8

9

$$10 \quad A_C^O = (2/N) \cdot \sum CUR_C[i] \cdot \cos(2\pi f_C(i/f_0)); \quad (2)$$

11

12 where both summations are taken over i from 1 to N .

13 The correlation between SIG_S and the sine wave of frequency

14 f_C is

15

$$16 \quad B_{S,C}^I = (2/N) \cdot \sum SIG_S[i] \cdot \sin(2\pi f_C(i/f_0)); \quad (4)$$

17

18 and the correlation between SIG_S and the cosine wave of
19 frequency f_C is

20

$$21 \quad B_{S,C}^O = (2/N) \cdot \sum SIG_S[i] \cdot \cos(2\pi f_C(i/f_0)); \quad (5)$$

22

23 where both summations are taken over i from 1 to N .

24 A preferred ratio of f_1 , f_2 and F_3 is 1, 2, 3 and
25 preferred frequencies are 1, 2 and 3 kHz. The useful
26 frequency range is believed to lie between 50 Hz and 50 kHz.

27 The calculation of the fields and currents, designated
28 by block 78, can also be performed using either dedicated
29 circuitry or a dedicated or shared microprocessor. The
30 amplitude of the current through each radiator A_C can be
31 calculated using:

32

$$33 \quad A_C = |A_C^I + jA_C^O| \quad (6)$$

34

35 and the magnitude of the field generated by each radiator,

36 $|B_{S,C}|$, can be calculated using:

$$|B_{s,c}| = |B_{s,c}^I + jB_{s,c}^O| \quad (7)$$

2

3 The phase between the current in radiator c and the
4 field sensed by sensor s, $\psi_{s,c}$, is

5

$$\phi_{s,c} = \arg(B_{s,c}^I + jB_{s,c}^O) - \arg(A_C^I + jA_C^O) - \psi_s^0 \quad (8)$$

7

8 where ψ_s^0 is the phase delay between the radiated field and
9 the field as read by sensors s. The amplitude of the field
10 generated by radiator c as sensed by sensor s is:

11

$$B_{s,c} = |B_{s,c}|, \quad \text{if } |\phi_{s,c}| < 90^\circ \quad (9a)$$

$$B_{s,c} = -|B_{s,c}|, \quad \text{if } |\phi_{s,c}| \geq 90^\circ \quad (9b)$$

14

15 The magnetic field for every possible location and
16 orientation of the sensor in the mappable space can be
17 obtained by using:

18 1) The field equations of the radiators used in a
19 specific embodiment,

20 2) The exact position and orientation of the radiators,
21 and

22 3) The current flowing through the radiators A_C .

23 Preferably the contributions of each field generator
24 are used to solve a set of field equations, which are
25 dependent upon the field form. Solving these equation sets
26 produces the location and orientation of the remote sensors,
27 most preferably simultaneously.

28 More particularly, the field equations are derived
29 specifically for each embodiment and are dependent on the
30 geometry and characteristics of the radiators. In the
31 preferred embodiment of the invention where the radiators
32 are coils, the field equations can be described as follows:

33 For a coil with N turns a radius R and a current I, the
34 radial field component at a distance r is

35

$$B_r(I, \vec{r}, \cos\theta) = (2\pi R^2 10^{-7} \cdot NI / r^3).$$

- 23 -

$$\sum (2i+1) P_{2i}(0) \cdot (R/r)^{2i} \cdot P_{2i+1}(\cos\theta) \quad (10)$$

2

3 and the tangential field component is:

4

$$B_\theta(I, \vec{r}, \cos\theta) = (2\pi R^2 10^{-7} \cdot NI/r^3) \sum P_{2i+2}(0) (R/r)^{2i} P_{2i+1}^1 \cos\theta$$

6

7 where the sums are from $l=0$ to $i=\infty$ and where $P_n(x)$ is a8 Legendre Polynomial of degree n , and calculated recursively

9 by:

$$P_0(x) = 1$$

$$P_1(x) = x \quad (12)$$

$$P_n(x) = 1/n [(2n-1)x P_{n-1}(x) - (n-1)P_{n-2}(x)]$$

13

14 $P_n^1(x)$ is a generalized Legendre Polynomial of degree n ,

15 and calculated by:

16

$$P_n^1(x) = -(n+1) \cdot x \cdot (P_n(x) - P_{n-1}(x)) / (1-x^2)^{1/2} \text{ for } |x| < 1$$

$$= 0 \quad \text{for } |x| = 1 \quad (13)$$

19

20 These field equations are correct for $r > R$ for a21 radiator located in location P . The field induced at22 location K is, as shown in Fig. 7, given by:

23

$$B = B_u \hat{O} + B_w \hat{W}$$

$$B_w = B_r \sin\theta + B_\theta \cos\theta \quad (14)$$

$$B_u = B_r \cos\theta - B_\theta \sin\theta$$

27

28 where \hat{O} is a unit vector in the radial direction of the29 radiator located at P and \hat{W} is a unit vector in the30 tangential direction of the radiator located at P . Using

31 this general field equation one can calculate the field at

32 point K generated by each of the radiators.33 The remote sensor orientation, denoted by \hat{V} determines34 the field sensed by this sensor at this location (K).

35

$$B \cdot \hat{V} = B_{\hat{V}} \quad (15)$$

36

1 Therefore the field sensed by a remote sensor is

2

$$3 \quad B_{\hat{V}} = B(\hat{P}, \hat{O}, I, R, \hat{V}) \quad (16)$$

4 where R and \hat{V} are the unknown variables, and \hat{O} , \hat{P} and I are
5 the known variables for any given coil.

6 In the example embodiment there are three radiators;
7 therefore there will be three known values of \hat{P} and three
8 known values of \hat{O} . The three sensors have a fixed and known
9 location and orientation in the remote object reference
10 frame. For each position and orientation of the remote
11 object, one can compute the location and orientation of each
12 sensor in the radiator reference frame and therefore compute
13 the field sensed, $B_{\hat{V}}$, for each radiator and each sensor. In
14 the case of the present location system, each field sensed
15 by each sensor from every radiator is measured and the field
16 equations are solved to obtain the location and orientation
17 of the remote object ($x, y, z, \epsilon, \xi, \text{ and } \zeta$).

18 The results of this approach for the three radiator,
19 three sensor system used here as an example, are nine non-
20 linear algebraic equations with six variables (namely, $x, y,$
21 z of the sensing means position and $\epsilon, \xi, \text{ and } \zeta$ for the
22 location sensor orientation) in the form of:

23

$$24 \quad ([F_{S,C}(x,y,z,\epsilon,\xi,\zeta) = B_{SC}]_{S=1,2,3})_{C=1,2,3} \quad (17)$$

25

26 In this embodiment of the invention, the nine sensor
27 readings ($B_{S,C}$) are the measured quantity, and by solving
28 this overdetermined system of equations (using a variety of
29 known numerical methods such as the Newton-Raphson method
30 for non-linear systems of equations or Multidimensional
31 Secant Methods, specifically Broyden's method), the location
32 and orientation of location sensor 14 is determined. A
33 description of several possible numerical methods for
34 solving such a set of equations is found in William H. Press
35 et al, "Numerical Recipes in C. The Art of Scientific
36 Computing", second edition, Cambridge University Press,

1 1992. The location sensor position and orientation are
2 displayed on monitor 27.

3 An ECG monitor may be used to synchronize the
4 acquisition of the signals from the sensor coils so as to
5 remove cardiac motion artifacts from the position
6 information. Furthermore, a reference sensor may be attached
7 to a portion of an organ being tested or treated, such as
8 the heart, which will be used to correct for breathing
9 motion or patient movement. In this way, the acquired sensor
10 positions may be referenced to the organ structure and not
11 to an absolute outside reference frame, which is less
12 significant.

13 In an analog based embodiment of signal processor 26,
14 some of the parameters are calculated using analog
15 circuitry. Fig. 8 is a schematic of one analog based
16 embodiment of signal processor 26. In this embodiment,
17 three sine and three cosine wave signals of frequency f_1 ,
18 f_2 , and f_3 , are used in addition to the SIG and CUR signals
19 used in the embodiment of Fig. 6. The SIG and CUR signals
20 are filtered by 12 phase sensitive filters (correlators) 80,
21 such as are shown in Fig. 9 to produce signals indicative of
22 the sine and cosine components of the SIG and CUR signals.

23 These analog signals are then passed to a set of A/D
24 converters 82. The fields and currents and positions are
25 calculated in the same manner as described above with
26 respect to Fig. 6.

27 Fig. 9 shows the expanded view of one possible
28 embodiment of one of the analog filter elements of Fig. 8.
29 Each analog filter unit has three inputs; a cosine wave
30 $\cos(2\pi f_c)$, a sine wave $\sin(2\pi f_c)$, and the signal, either one
31 of SIG_s or CUR_s from which the frequency component f_c is to
32 be extracted. Within the analog filter unit the signal is
33 multiplied by $\sin(2\pi f_c)$ and $\cos(2\pi f_c)$ in multipliers 84 and
34 86. The results are passed through low pass filters 88 and
35 90 to obtain the desired components of the signal.

36 The description above primarily concerns acquiring

1 information by a set of two or more sensors that is used to
2 determine the position and orientation of a remote object or
3 a point on a remote object such as a medical device or
4 instrument. It is also within the scope of the invention
5 that a remote object will have more than one set of sensors,
6 preferably from 2 to 6 sets of sensors, that will provide
7 sufficient parameters to determine the shape and/or
8 configuration of a remote object, preferably relative to a
9 reference frame. For example, if the catheter has
10 additional sets of sensors located proximal to its distal
11 tip, it would be possible to determine the shape and/or
12 configuration of portions of the catheter. Similarly, for
13 another invasive procedure such as a sigmoidoscopy or
14 colonoscopy, it may be possible to determine the shape
15 and/or configuration of some or all of the scope used.

16 The equipment necessary to practice the invention is
17 mostly conventional. In one embodiment of the invention,
18 the controller is a simple off-the-shelf 486 IBM compatible
19 computer. The A/D boards are commercially available and
20 have the characteristic of being able to sample at least 8
21 channels with a sampling frequency of between 500 - 40,000
22 samples per second on each channel. An example of such an
23 A/D Board is the National Instruments AT-MIO-16X that is
24 available from National Instruments, Texas, USA. The D/A
25 function is achieved using commercially available 8-21 bit
26 resolution D/A boards. Examples of such a D/A are the
27 National Instruments A/D,D/A Board AT-MIO-16X or National
28 Instruments DSP model AT-DS2200. The radiation driver
29 amplifiers are commercially available, with 2-16 ohms
30 output impedance and an output power of 60-500 watts. An
31 example of such amplifiers is the Inkel amplifier type NA-
32 420, from Inkel of Seoul, Korea. The radiators are also
33 commercially available and have the following
34 characteristics: 1-6 cm radius, 0.5-3 cm thickness, and
35 100-500 turns made of copper wire of diameter 0.1 -0.95 mm.
36 A specific example of such a coil could be coils having a 4

1 cm radius, 1 cm thickness with 151 turns of copper wire of
2 0.41 mm diameter.

3 While the sensor described above is preferred, other
4 sensors may be suitable for some applications, such as Hall
5 effect sensors, for example those available from Allegro
6 Micro Systems, Inc., USA or magneto-resistor sensors,
7 sensors, flux gate magnetic sensors, and/or other magnetic
8 flux sensors.

9 Controller 40 represents an assemblage of units to
10 perform intended functions. For example, such units may
11 receive information or signals, process information,
12 function as a controller, display information, and/or
13 generate information or signals. Typically controller 40
14 may comprise one or more microprocessors.

15 In accordance with a preferred embodiment of the
16 invention, active portion 16 of catheter 10 is a forward
17 looking ultrasound send/receive transducer. Such a
18 transducer can give a one-dimensional map of the acoustic
19 properties of the material lying in front of it by radiating
20 a focused beam of pulsed acoustic energy and then measuring
21 the echoes of the beam reflected by changes in acoustic
22 properties along the path of the beam. In order to provide a
23 three dimensional image it is necessary to change the
24 direction of the beam, preferably without changing its
25 position by a great amount.

26 In particular, such a steerable, one dimensional
27 acoustic transducer can be used to map the heart walls or
28 blood vessels, ultrasonically, from inside the heart. When
29 coupled with a reference location sensor at a reference
30 point on the heart and ECG gating of the acoustic pulses,
31 such a transducer can generate the information required to
32 form a three dimensional image of the heart or blood vessels
33 or any other organ, at one or several different phases of
34 the heart cycle.

35 The principle of two preferred embodiments of a
36 steering mechanism are shown in Figs. 10A-10D and 11

1 respectively. Fig. 10A shows a steering mechanism 92 that
2 fits into the distal end of a catheter and comprises two
3 steering wires 94 attached to a steering head 96. Head 96 is
4 formed of a relatively flexible material such as stainless
5 steel and is slit along its axis, each side of the split
6 being attached to one of wires 94. Such a head may be
7 manufactured by attaching two wires (94) at their end and
8 then flattening the wires to form a more easily bent
9 structure.

10 Attached to the distal end of the steering head is a
11 relatively rigid housing containing locating sensor 14 and
12 active portion 16 which, in the present preferred
13 embodiment, is an ultrasonic send/receive transducer. At
14 least head 96 and wires 94 are encased in a catheter sheath
15 104 which is not shown in Figs. 10A-10C for clarity of
16 presentation. This steering mechanism can also be used for
17 other active portion types such as for electropysiologic
18 mapping procedures and for improved steering of catheters or
19 many types, with or without location sensing.

20 In Fig. 10B one of wires 94 has been shortened as
21 compared with the other wire. Since the catheter sheath
22 holds the wires together, the result of such shortening of
23 one wire is bending of the head, which is facilitated by the
24 axial slit. Locating sensor 14 and active portion 16 are
25 rigidly attached so that measurement of position and
26 orientation of the locating sensor will give the position
27 and orientation of the active portion (ultrasound
28 transducer). By varying the angle of bending and rotating
29 the catheter, imaging over nearly 360° image can be
30 achieved. Additionally or alternatively, as shown in Fig.
31 10C, the amount of rotation can be reduced by shortening the
32 other wire and which causes bending in the other direction.
33 Slight motion of the transducer can be corrected by a simple
34 translation of the acquired one dimensional image associated
35 with the particular position.

36 Fig. 10D shows a mechanism 98 placed at the proximal

1 end of the catheter for changing the relative lengths of
2 wires 94. A handle 100 comprises a housing 102 to which
3 catheter sheath 104 is attached. The proximal end of wires
4 94 are formed in a loop (for example by welding the ends of
5 the wire) and wrapped around a spindle 106 which is
6 preferably fixed and which forms a frictional contact with
7 the wires.

8 A lever 108 is rotatably attached near its center at a
9 pin 110 to the housing and is attached at one end to wire 94
10 and at the other end to a slider 112 which is slidable
11 parallel to the housing. When the slider is moved, one of
12 the wires 94 at the distal end is lengthened with respect to
13 the other.

14 Fig. 11 shows the distal end of a catheter having an
15 alternative steering mechanism. A relative rigid sleeve 114
16 is placed within cathode sheath 104. Sleeve 114 can be
17 axially displaced relative to the sheath from the proximal
18 end of the catheter.

19 The distal end of sleeve 104 is formed with a disk 116
20 through which a relatively less rigid wire 118 passes. Wire
21 118 is formed with a permanent bend near its distal end at
22 which end, position sensor 14 and active portion 16 are
23 attached. Axial movement of sleeve 104 straightens wire 118
24 resulting in a change in orientation of both the position
25 sensor and the active portion. If wire 118 is sited off
26 axis, then rotating the wire will rotate the catheter.

27 It should be understood that steering of acoustic beams
28 may also be achieved by a moving mirror or by a phased array
29 ultrasonic transducer, and that such a mirror or other
30 arrangement may be present in the active portion. Such
31 active scanning may supplement or replace the passive
32 steering provided by the mechanisms of Figs. 10 and 11.

33 Fig. 12 shows a simplified system block diagram of
34 ultrasonic acquisition and image formation in accordance
35 with a preferred embodiment of the invention. An image
36 sensor 120, such as the ultrasound sensor described above,

1 transmits an acoustic pulse 122 in response to a signal
2 received from a transmitter driver circuit 124. An acoustic
3 echo 126 (generally comprising several echoes) is received
4 by the image sensor which produces an echo signal, which
5 when amplified, is sent to a receiver processing circuit 128
6 which generates a one dimensional "image" at its output 130.
7 Information identifying the heart phase of the image may
8 also be present at output 130 which may comprise a plurality
9 of output ports. In one embodiment of the invention,
10 especially useful for heart imaging, the acquisition of the
11 image is made in response to signals received from an ECG
12 monitor 132. This allows for acquisition of images at a
13 particular portion of the heart cycle so that the various
14 one-dimensional images can be easily reconstructed into a
15 three dimensional image.

16 In particular, if the most significant echo is used as
17 the measure of the distance from the ultrasonic sensor to
18 the chamber along the measurement direction of the sensor,
19 then the collection of such distances (referenced to a
20 reference point in the chamber) will allow the
21 reconstruction of the surface morphology.

22 Fig. 13 shows a simplified block diagram of a three
23 dimensional image reconstruction system which utilizes a
24 series of one dimensional images generated by the circuitry
25 of Fig. 12 and continuous sensed location and orientation
26 information generated by the position locator and its
27 associated circuitry as described above. In general it is
28 useful to acquire the sensed location and orientation to
29 coincide with the acquisition of each one-dimensional image.
30 One of the various methods described above for steering the
31 distal tip of the catheter is used to acquire a plurality of
32 one dimensional images with a plurality of orientations. An
33 automatic mechanism may be used to continuously change the
34 orientation of the imaging head in accordance with the
35 principles of Figs. 10 and 11 and to rotate the catheter so
36 that operator intervention is not required.

1 An image reconstruction processor 132 orients and
2 references the individual one dimensional images in
3 accordance with the sensed location and orientation
4 information and forms a 3-D image which can be presented on
5 an image display 13 either in the form of a series of two
6 dimensional slices or a full three dimensional
7 reconstruction. When images at different points in the heart
8 cycle are acquired, the image displayed may be a cine image
9 of the reconstruction.

10 In a preferred embodiment of the invention a two
11 dimensional image is acquired by the ultrasound sensor which
12 can be a phased array of acoustic crystals of a single
13 crystal in conjunction with a mirror rotating about an axis
14 that deflects the ultrasonic beam in a predetermined path.

15 In a preferred embodiment of the invention active
16 portion 16 comprises a sensor for sensing electrical signals
17 generated at selectable positions on the heart. As described
18 below, such sensings of electrical signals can be used to
19 map the electrical activity of the heart. The active portion
20 may also include an electrode useful for pacing the heart
21 and/or for ablating a portion of the heart. Such ablation is
22 especially useful in the treatment of the most common lethal
23 cardiac arrhythmia, ventricular tachycardia (VT), i.e., very
24 rapid and ineffectual contractions of the heart muscle. VT
25 is the cause of death of approximately 300,000 people
26 annually. It is also useful in the treatment of other
27 arrhythmias.

28 A catheter useful for electrical mapping of the
29 heart/ablation is shown schematically in Fig. 14.

30 Active portion 16 comprises a conducting tip,
31 preferably of platinum, having a length of between 1-12 mm,
32 preferably about 2 mm. The tip is connected via a tip
33 electrode lead-in wire 138 to a switch at the proximal end
34 of the cathode which switches the tip to a source of voltage
35 for pacing or/ablating or to a detector for detecting
36 electrical signals generated by the heart. A conducting ring

1 electrode 136 is placed, proximal to locating sensor 14, on
2 the outside of catheter sheath 104 and is connected to
3 ground or to a recorder via a return lead 140. When used for
4 pacing, as described below, a 1-10 ma pulse is applied
5 between tip 16 and ring electrode 136. When used for
6 ablation RF energy at about 0.5 MHz and 10-100 V is applied
7 for 10-200 sec.

8 Locating sensor 14 is rigidly attached to the tip and
9 the sensor and tip may be manipulated by an eccentric wire
10 142. The twisted wire leads are preferably shielded by a
11 shield 144 to reduce pickup from the relatively high
12 voltages carried by leads 138 and 140.

13 Preferably, an electrically insulating heat shield 146
14 is placed between the tip and the locating sensor.

15 Fig. 15 is a schematic block diagram for acquiring a
16 basic electrocardiogram map in accordance with a preferred
17 embodiment of the invention. Using a transesophageal
18 echocardiograph in the preferred embodiment, a multiplane
19 image of the heart chambers is acquired prior to the mapping
20 study. The image is acquired only during a fiducial point
21 in time during the cardiac cycle. In the preferred
22 embodiment, the image is acquired at end-diastole in
23 response to an end diastole synch-signal. A three-
24 dimensional image of the heart chambers is reconstructed
25 indicating the endocardial morphology and the location of
26 one or more reference catheters within the heart chamber.
27 This image can be acquired by a 3-D transesophogal
28 ultrasound image, by a CT scanner, by an MRI scanner or by
29 other imaging techniques. The image can also be constructed
30 by touching the catheter to the surface of the chamber
31 (endocardium) in a number of places and measuring the
32 positions. These points can then be used to describe a thee
33 dimensional surface which represents the chamber
34 surface.

35 In the previous PCT and US applications (PCT/US94/08352
36 filed July 20, 1994 and 08/094,539 respectively), in which
- 33 -

1 fewer than six location and orientation values were
2 determined, reference locatable catheters were place at
3 three positions in the heart to form a reference plane
4 against which the position of the active catheter was
5 referenced. Preferably, these reference locatable catheters
6 were placed, for example, in the right ventricular apex, the
7 right atrial appendage, and the pulmonary artery at the
8 level of the pulmonary valve, respectively. When a
9 reference catheter having a location sensor 14 as described
10 hereinabove is used for reference purposes, only a single
11 sensor is required to define the relative location and
12 orientation of the mapping catheter. While any of these
13 locations can be used, it is presently preferred to place
14 the reference sensor in the distal coronary sinus.

15 Fig. 16 is a schematic block diagram for illustrating
16 the computerized endocardial activation mapping algorithm
17 (used during sinus rhythm mapping and during ventricular
18 tachycardia mapping). A visible or audible indicator
19 preferably indicates the beginning of a data point
20 acquisition. Both electrical activity and
21 location/orientation data are acquired for each point in
22 the map.

23 The acquisition of catheter location information is
24 shown in left branch of the block diagram of Fig. 16. The
25 mapper electrode is in steady and stable contact with the
26 endocardium. Stable contact is determined by measuring the
27 stability of the location reading, the stability of the
28 sensed electrograms and the impedance of the contact.

29 The position and orientation of the locating sensor in
30 the mapping catheter are determined continuously in
31 accordance with the method described above and are saved in
32 response to an end diastole synch signal. The mapper
33 catheter tip is localized relative to the reference catheter
34 by finding the difference in each of the six dimensions of
35 the location and orientation. Generally speaking, for the
36 present application the orientation of the mapper cathode is

1 not required, however, it must be acquired to properly
2 transform its location and orientation to an internal heart
3 coordinate system.

4 Simultaneously, the activation time of the heart at the
5 mapper cathode tip is determined as shown on the right side
6 of Fig. 16. First the local electrocardiogram at the tip of
7 the mapper catheter is acquired and the activation time is
8 calculated based on comparing the amplitude and slope of the
9 local electrocardiogram to a template or manually by the
10 user. The local activation time is then defined with
11 reference to the activation time measured by an ECG terminal
12 on the skin of the patient.

13 The process of data acquisition can be terminated by
14 the user, or can be evaluated by an "evaluate activation
15 map" algorithm described below, that examines the already
16 acquired activation map for the density of information
17 relative to the spatial gradient of activation times. This
18 algorithm can indicate the next preferable site for
19 activation time detection. The catheter is moved by the
20 user to the new site, and the process of mapping continues.

21 During VT a data point is determined about every 4 to 6
22 heart beats. Thus, approximately 15 to 25, typically about
23 20, data points can be determined each minute.

24 Fig. 17 is a schematic block diagram for illustrating
25 the computerized pace mapping algorithm. A visible or
26 audible indicator indicates the beginning of a data point
27 acquisition. Acquisition of position information is similar
28 to that for Fig. 16 except that the average mapper location
29 in the previous n heartbeats (n is the moving average window
30 duration) is calculated.

31 The right side of Fig. 17 shows the determination of
32 the ACI (AutoCorrelation Index) in a pace mapping mode.

33 In a "pace mapping mode" an ECG processor acquires ECG
34 data while the patient's heart is paced by an external
35 source at a rate similar to the patient's arrhythmia cycle
36 length. The ECG data is also acquired from the body surface

1 electrograms, and the signals are stored as a segment of ECG
2 with a length of several cycles. The signal acquired is
3 subjected to automatic comparison with the patient's own VT
4 signal (see Fig. 18). The comparison between arrhythmia
5 morphology and paced morphology is performed in two stages:
6 First, the phase shift between the template VT signal and
7 the paced ECG morphology is estimated using minimal error or
8 maximal cross-correlation for two signals. Then, using this
9 phase shift estimated from an index ECG channel, the
10 similarity of the VT and the paced ECG morphology is
11 measured as the average of the cross-correlation or the
12 square error of the two signals of all channels recorded.

13 This two-stage calculation is repeated each time using
14 a different ECG channel as the index channel for determining
15 the phase shift.

16 At the end of this procedure the minimal error or the
17 maximal cross-correlation found will be reported to the
18 operator as the ACI of this pacing site.

19 Fig. 18 is a schematic block diagram illustrating an
20 algorithm used to calculate the cross-correlation index
21 while pace-mapping in accordance with a preferred embodiment
22 of the invention. Body surface ECG data is acquired at two
23 stages. First, during spontaneous or pacing induced VT, and
24 second, during pacing the endocardium at different sites.
25 The ECG data acquired during VT are signal averaged, and a
26 template is constructed (T_{ch} , for each channel recorded).
27 During endocardial pacing the ECG data is acquired, and the
28 same number of beats (N) is acquired to calculate the signal
29 averaged QRS (P_{ch} , for each channel recorded). The
30 algorithm then calculates the phase shift between P_{ch} and
31 T_{ch} , which yields for the first channel the maximal cross-
32 correlation. This time shift is used to shift the remaining
33 channels and calculate for them the cross-correlation. All
34 cross-correlations for all channels are summarized and
35 stored. The algorithm then uses the next channel recorded
36 to calculate the time shift that will cause maximal cross-

1 correlation in this channel. Now this time shift is applied
2 for all cross-correlations between P_{Ch} and T_{Ch} , and again
3 all cross-correlations are summarized. This procedure is
4 repeated for all channels, and the maximal cross-correlation
5 achieved is used as the value of the cross-correlation of
6 the T_{Ch} and the P_{Ch} at this site on the endocardium.

7 FIG. 19 is a schematic block diagram for illustrating
8 the output configuration of the present embodiment. A
9 quasi-static picture of the heart chambers is presented as
10 3-D reconstruction of a basic image acquired prior to or
11 during the study as previously described. Superimposed on
12 the image is the location of the mapping/ablation catheter
13 (corrected for the movement of the reference catheter) and
14 the current and previous information acquired from the
15 mapping study. This information may include, when
16 appropriate, the activation times (presented using a color
17 code at each acquisition site) or cross-correlation index
18 (ACI) for each point in the pace map. Furthermore, the map
19 can represent in the color coding the duration of the local
20 electrograms, the presence of fragmented activity as well as
21 various other variables calculated by the electrophysiologic
22 processor.

23 The above principles can be applied for mapping other
24 structures of the body, for example, of the urinary bladder,
25 brain, or gastrointestinal tract. Dependent upon the
26 examination technique, the catheter may be replaced by a
27 needle whose tip is the locatable sensor port.

28 At each stage (sinus rhythm mapping, pace mapping and
29 VT mapping) after each data point is acquired, all available
30 information is reassessed for two purposes: first, to
31 suggest to the operator the next site for data acquisition,
32 and second, to test the available information to propose a
33 site for ablation.

34 Two algorithms are running simultaneously to perform
35 this procedure:

36 (1) Mapping guidance algorithm. This algorithm uses as

1 an input the available mapped information of a certain
2 variable (e.g., local activation time during sinus rhythm).
3 The algorithm calculates the spatial derivative of the
4 mapped variable (i.e., activation time in this example) and
5 calculates the next best location for adding another data
6 point when the objective function is regularizing the
7 spatial gradients of the mapped variable. For example, this
8 algorithm will suggest that more data points be acquired in
9 areas in which the mapped variable is changing significantly
10 over a short distance.

11 The location suggested by the algorithm is be presented
12 to the operator as a symbol on the display. The same
13 display already shows the basic image of the heart chamber
14 and the current location of the mapping/ablation catheter.
15 Therefore, the operator will move the mapping/ablation
16 catheter to reach the suggested location for further data
17 acquisition.

18 This algorithm is most beneficial during VT mapping,
19 where the available time for data acquisition is limited by
20 the adverse hemodynamic effects of the arrhythmia.
21 Therefore, such an algorithm which examines the available
22 data points of a map in real-time and immediately suggests
23 the next site for acquisition is very useful.

24 (2) Prognosing likelihood of successful ablation
25 algorithm. This algorithm is a user-defined set of
26 hierarchical rules for evaluating the acquired information
27 such as the rules given immediately below. The operator is
28 expected to grade the importance of the specific information
29 acquired in the mapping/ablation procedure, as to its
30 likelihood to identify the correct site for ablation.

31 Grading of mapping results suggesting the likelihood of
32 successful ablation at that site (A = highly likely
33 successful and D = least likely successful):

34 (a) The identification of a typical re-entrant pathway
35 on VT mapping with an identifiable common slow pathway -
36 Grade A;

1 (b)The identification of a site with over 90%
2 correlation index in the pace map - Grade B;

3 (c) The identification of a site where VT was terminated
4 with a non-capture premature stimulus - Grade C; and

5 (d) The identification of pre-potential maps recorded
6 during VT, which are similar to diastolic potential maps
7 recorded during sinus rhythm - Grade D.

8 Other types of electrographic maps of the heart are
9 also possible. By use of variables determined from paced or
10 non-paced acquisitions of electrographic data, the following
11 additional maps can be generated:

- 12 (1) Sinus rhythm activation map (isochronal map);
- 13 (2) Diastolic potential occurrence time map
- 14 (3) Local latency isochronal map during pace mapping;
- 15 (4) Activation time isochronal map during VT; and
- 16 (5) Pre-potential isochronal map during VT mapping.

17 Also, the sites where VT was terminated by a non-
18 captured premature stimulus can be presented.

19 The acquisition of these maps and of other factors
20 suitable for mapping and procedures for their determination
21 as well as additional details of the above mapping
22 procedures can be found in the above mentioned U.S. Patent
23 Application Number 08/094,539 and PCT Application
24 PCT/US94/08352.

25
26
27
28
29
30
31
32
33
34
35
36

CLAIMS

- 1
2 1. A locating system for determining the location and
3 orientation of an invasive medical instrument relative to a
4 reference frame, comprising:
5 a plurality of field generators which generate known,
6 distinguishable fields in response to drive signals;
7 a plurality of sensors situated in the invasive medical
8 instrument proximate the distal end thereof which generate
9 sensor signals in response to said fields; and
10 a signal processor which has an input for a plurality
11 of signals corresponding to said drive signals and said
12 sensor signals and which produces the three location
13 coordinates and three orientation coordinates of a point on
14 the invasive medical instrument.
15
16 2. The locating system according to claim 1 wherein one of
17 the plurality of field generators or sensors comprises three
18 distinguishable, non-overlapping, generators or sensors.
19
20 3. The locating system of claim 1 wherein said plurality
21 of field generators comprises three distinguishable, non-
22 overlapping, generators and said plurality of sensors
23 comprises three distinguishable, non-overlapping sensors.
24
25 4. The locating system of any of claims 1-3 wherein each
26 sensor comprises a coil.
27
28 5. The locating system of claim 4 wherein said plurality
29 of coils have axes which intersect within a coil.
30
31 6. The locating system of claim 4 or claim 5 wherein said
32 plurality of coils comprises three coils and wherein said
33 coils have axes which do not all intersect in a point.
34
35 7. The locating system of any of the preceding claims
36 wherein the fields generated by each of the field generators

1 have a different frequency, a different phase, or both a
2 different frequency and a different phase.

3

4 8. The locating system of any of the preceding claims,
5 wherein the field generated by each field generator has a
6 different frequency.

7

8 9. The locating system of claim 8, wherein the frequencies
9 of the field generators are each integer multiples of a
10 given frequency.

11

12 10. The locating system of any of claims 7-9, wherein the
13 signal processor cross-correlates the signals corresponding
14 to the drive and sensor signals.

15

16 11. The locating system of claim 9, wherein the signal
17 processor cross-correlates the signals corresponding to the
18 drive and sensor signals and wherein the duration of the
19 cross-correlation of the inputs is the minimal common
20 product of the integer multipliers divided by the given
21 frequency.

22

23 12. The locating system of claim 10 or claim 11, wherein
24 the results of the cross-correlation are used to calculate
25 the contribution of each field generator to the signal
26 generated by each said sensor.

27

28 13. The locating system of any of the preceding claims
29 wherein the fields are AC magnetic fields.

30

31 14. The locating system of claim 13, wherein the AC
32 magnetic fields are continuous fields.

33

34 15. The locating system of any of the preceding claims and
35 including a display system for displaying the position of
36 the point on the invasive medical instrument.

1 16. The locating system of any of the preceding claims
2 wherein there is an additional sensor on a portion of the
3 invasive medical instrument which senses a local condition.

4

5 17. The locating system of claim 16 wherein the additional
6 sensor senses local electrical signals and transfers them to
7 terminals external to the patient's body.

8

9 18. The locating system of claim 17, wherein the signals are
10 electrical signals from the endocardium of the patient's
11 heart.

12

13 19. The locating system of claim 18, wherein the signal
14 processor processes the position and orientation coordinate
15 signals and the local electrical signals acquired at a
16 plurality of points on the endocardium to generate a map
17 that represents the propagation of electrical signals
18 through tissue in the patient's body.

19

20 20. The locating system of any of claims 16-22 wherein the
21 additional sensor is operative for supplying electrical
22 energy to the endocardium for ablating a portion of the
23 endocardium.

24

25 21. The locating system of any of claims 1-16 and including
26 an electrode adapted for supplying electrical energy to the
27 endocardium for ablating a portion of the endocardium.

28

29 22. The locating system of claim 16 wherein the additional
30 sensor is an ultrasonic transmitter/receiver.

31

32 23. The locating system of claim 22 wherein the ultrasonic
33 transmitter/receiver provides a less than three dimensional
34 representation of the acoustic properties of tissue beyond
35 the distal end.

36

1 24. The locating system according to claim 23 wherein the
2 distal end is deflectable.

3

4 25. The locating system according to claim 24 and including
5 image reconstruction circuitry which receives a plurality of
6 said less than three dimensional representations acquired at
7 different orientations of the distal end and produces a
8 three dimensional map of the acoustic properties of tissue
9 at least partially surrounding the distal end.

10

11 26. The locating system of any of the preceding claims and
12 further comprising a reference instrument which includes a
13 plurality of sensors situated in the reference instrument,
14 wherein said display system displays the position of the
15 point on the invasive medical instrument relative to the
16 position of a point on the reference instrument.

17

18 27. The locating system of claim 26, wherein the locating
19 system comprises only a single reference instrument.

20

21 28. The locating system of claim 26 or claim 27 wherein the
22 reference instrument is an invasive medical instrument and
23 wherein said sensors are are situated proximate the distal
24 end of thereof.

25

26 29. An imaging system for intrabody ultrasonic imaging
27 comprising:

28 a invasive medical instrument having an axial-looking
29 ultrasonic imaging transducer at the distal end thereof
30 which generated a representation of the acoustic properties
31 of tissue beyond the distal end;

32 means for manipulating the distal end to change the
33 orientation thereof; and

34 image reconstruction circuitry which receives a
35 plurality of said representations acquired at different
36 orientations of the distal end and produces a three

1 dimensional map of the acoustic properties of tissue at
2 least partially surrounding the distal end from said
3 plurality of representations.

4
5 30. The imaging system of claim 29 and further comprising:
6 a plurality of field generators which generate known,
7 distinguishable fields in response to drive signals;
8 a plurality of sensors situated in the invasive medical
9 instrument proximate the distal end thereof which generate
10 sensor signals in response to said fields; and
11 a signal processor which has an input for a plurality
12 of signals corresponding to said drive signals and said
13 sensor signals and which produces three location coordinates
14 and three orientation coordinates of the a point on the
15 transducer.

16
17 31. The imaging system of claim 29 or claim 30 wherein said
18 representations are one or two dimensional representation.

19
20 32. The system of any of the preceding claims wherein the
21 invasive medical instrument is a catheter or endoscope.

22
23 33. A method of determining the position and orientation of
24 an invasive medical instrument having a distal end,
25 comprising:

26 (a) generating a plurality of distinguishable,
27 geometrically different AC magnetic fields;

28 (b) sensing the AC magnetic fields at the sensors at a
29 plurality of points proximate the distal end; and

30 (c) computing six dimensions of position and
31 orientation of a portion of the invasive medical instrument
32 responsive to signals representative of the generated
33 magnetic fields and the sensed magnetic fields.

34
35 34. A method according to claim 33 wherein the plurality of
36 distinguishable, geometrically different fields comprises

1 three such fields.

2

3 35. A method according to claim 33 or claim 34 wherein the
4 AC magnetic field is sensed at three points of the invasive
5 medical instrument.

6

7 36. A method according to any of claims 33-35 wherein the
8 invasive medical instrument is a catheter or endoscope.

9

10 37. An ultrasonic intra-body imaging method comprising:

11 (a) inserting an ultrasonic transducer into the body,
12 said ultrasonic transducer producing a representation of the
13 acoustic properties of tissue beyond an end of the
14 transducer;

15 (b) manipulating the orientation of the transducer to
16 provide a plurality of said representations; and

17 (c) constructing a three dimensional map of the
18 acoustic properties of the tissue in a region at least
19 partially surrounding the end of the transducer from said
20 plurality of representations.

21

22 38. A method according to claim 37 and further comprising:

23 determining the six dimensions of position and
24 orientation of the transducer for each of the
25 representations.

26

27 39. A method according to claim 37 or claim 38 wherein the
28 representation is a less than three dimensional
29 representation.

30

31 40. A invasive medical instrument comprising a plurality of
32 magnetic field sensors proximate the distal end thereof.

33

34 41. The instrument of claim 40 wherein each sensor
35 comprises a coil.

36

1 42. The instrument of claim 41 wherein said plurality of
2 coils have axes which intersect within a coil.

3

4 43. The instrument of any of claims 40-42 wherein the
5 plurality is three.

6

7 44. The instrument of claim 41 or claim 42 wherein said
8 plurality of coils comprises three coils and wherein said
9 three coils have axes which do not all intersect in a point.

10

11 45. The instrument of any of claims 40-44 and further
12 comprising an ultrasound transducer at said distal end.

13

14 46. The instrument of claim 45 wherein said ultrasound
15 transducer provides a representation of the acoustic
16 properties of tissue beyond and along the axis of the
17 catheter.

18

19 47. The instrument of claim 46 wherein said representation
20 is a one dimensional representation.

21

22 48. The instrument of claim 46 wherein said representation
23 is a two dimensional representation.

24

25 49. The instrument of any of claims 40-44 and further
26 comprising an electrical probe at said distal end.

27

28 50. The instrument of claim 49 wherein said electrical
29 probe is adapted to sense electrical signals generated by
30 tissue which is in contact and conduct said signals to the
31 proximal end of the catheter.

32

33 51. The instrument of claim 49 or claim 50 wherein said
34 electrical probe is adapted to supply an ablative electrical
35 signal to tissue contacting said probe.

36

1 52. The instrument of any of claims 40-44 and including a
2 sensor for measuring local chemistry at the distal end.

3
4 53. The instrument of any of claims 40-52 wherein said
5 instrument is a catheter or endoscope.

6
7 54. The instrument of any of claims 40-53 and also
8 including means for changing the orientation of the distal
9 end.

10
11 55. The instrument of claim 54 wherein the means for
12 changing the orientation comprises;

13 a relatively more flexible wire passing through the
14 medical instrument that is attached to the distal end and
15 has a bend near the distal end;

16 a relatively more rigid sleeve which is straight near
17 the distal end and which slideably holds the wire thereat,
18 whereby when the sleeve is slid over the wire, the wire and
19 distal end are straightened.

20
21 56. An instrument according to claim 55 wherein instrument
22 has a lengthwise axis and wherein the wire is sited off the
23 axis of the instrument.

24
25 57. An instrument according to claim 54 wherein the means
26 for changing the orientation comprises;

27 a flat relatively flexible portion being slit along a
28 portion of the length thereof to form two portions which are
29 attached at a first end thereof, said first end being
30 attached to the distal end of the instrument;

31 a pair of wires, one end of each of which being
32 attached to one of said portions at a second end thereof;
33 and

34 means for changing the relative lengths of the wires
35 whereby the flexible element is bent, thereby steering the
36 distal end of the instrument.

1 58. Apparatus for steering the distal end of an invasive
2 medical instrument, comprising:

3 a relatively more flexible wire passing through the
4 catheter, that is attached to the distal end and has a bend
5 near the distal end;

6 a relatively more rigid sleeve, that is straight near
7 the distal end and which slideably holds the wire thereat,
8 whereby when the sleeve is slid over the wire, the wire and
9 distal end are straightened.

10

11 59. Apparatus according to claim 58 wherein instrument has
12 a lengthwise axis and wherein the wire is sited off the axis
13 of the instrument.

14

15 60. Apparatus for steering the distal end of an invasive
16 medical instrument comprising:

17 a flat relatively flexible portion being slit along a
18 portion of the length thereof to form two portions which are
19 attached at a first end thereof, said first end being
20 attached to the distal end of the instrument;

21 a pair of wires, one end of each of which being
22 attached to one of said portions at a second end thereof;
23 and

24 means for changing the relative lengths of the wires
25 whereby the flexible element is bent, thereby steering the
26 distal end of the instrument.

27

28 61. Apparatus according to any of claims 58-60 wherein the
29 invasive medical instrument is a catheter or endoscope.

30

31 62. A method of producing a three dimensional image of the
32 internal surface of an internal body organ comprising:

33 measuring the distance to said surface at a plurality
34 of orientations from within the internal surface; and

35 assembling the distances to form an image of the
36 surface.

1 63. A method according to claim 62 wherein the measurement
2 of distances is made from a plurality of points within the
3 organ.

4

5 64. A method according to claim 62 or claim 63 wherein the
6 measurement of distances is preformed utilizing an
7 ultrasonic transducer.

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

1/19

FIG. 1

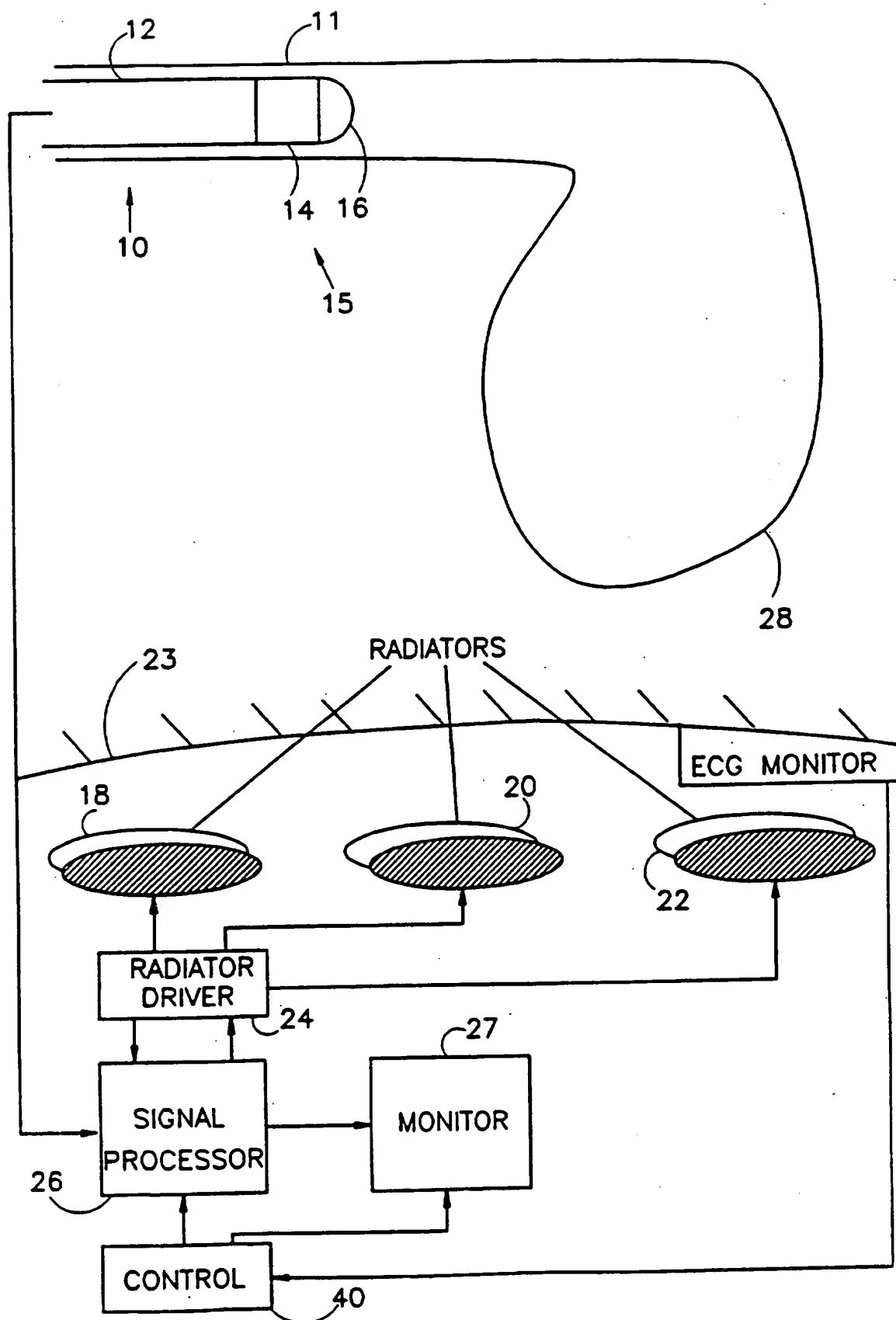
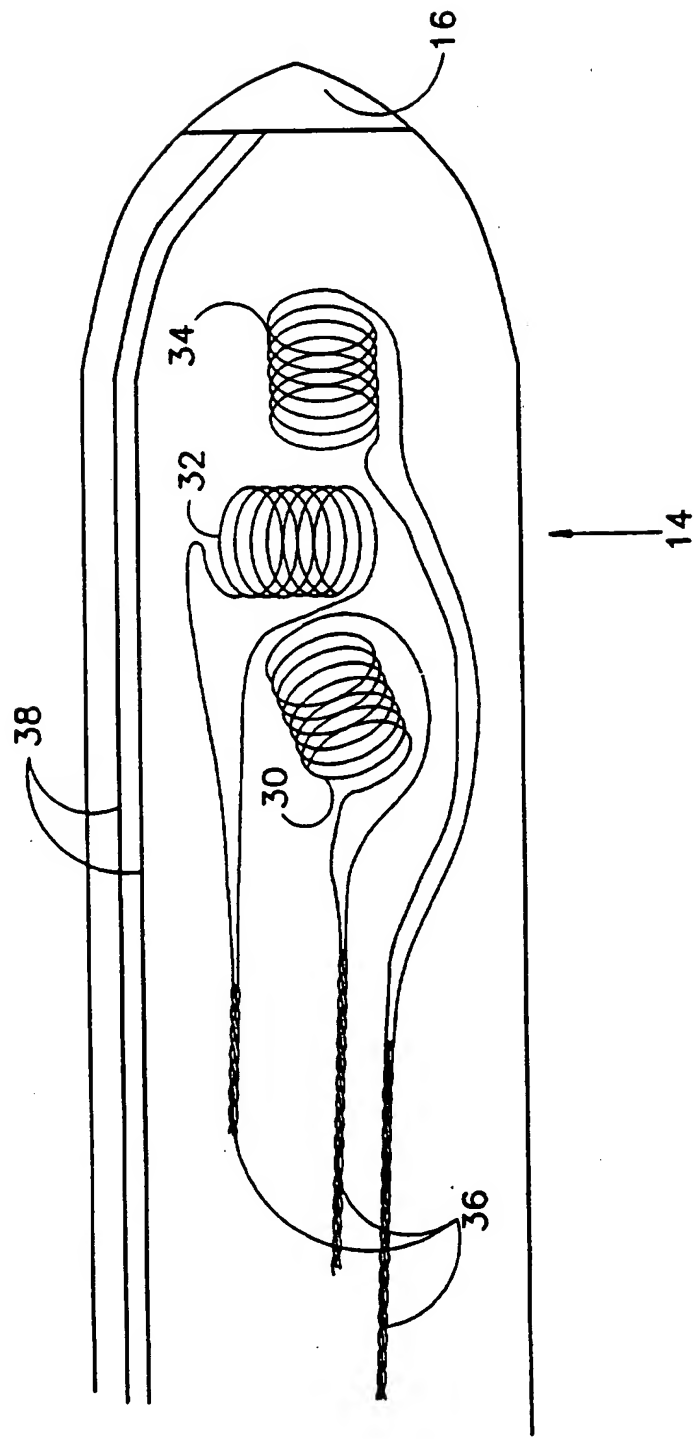


FIG. 2



3/19

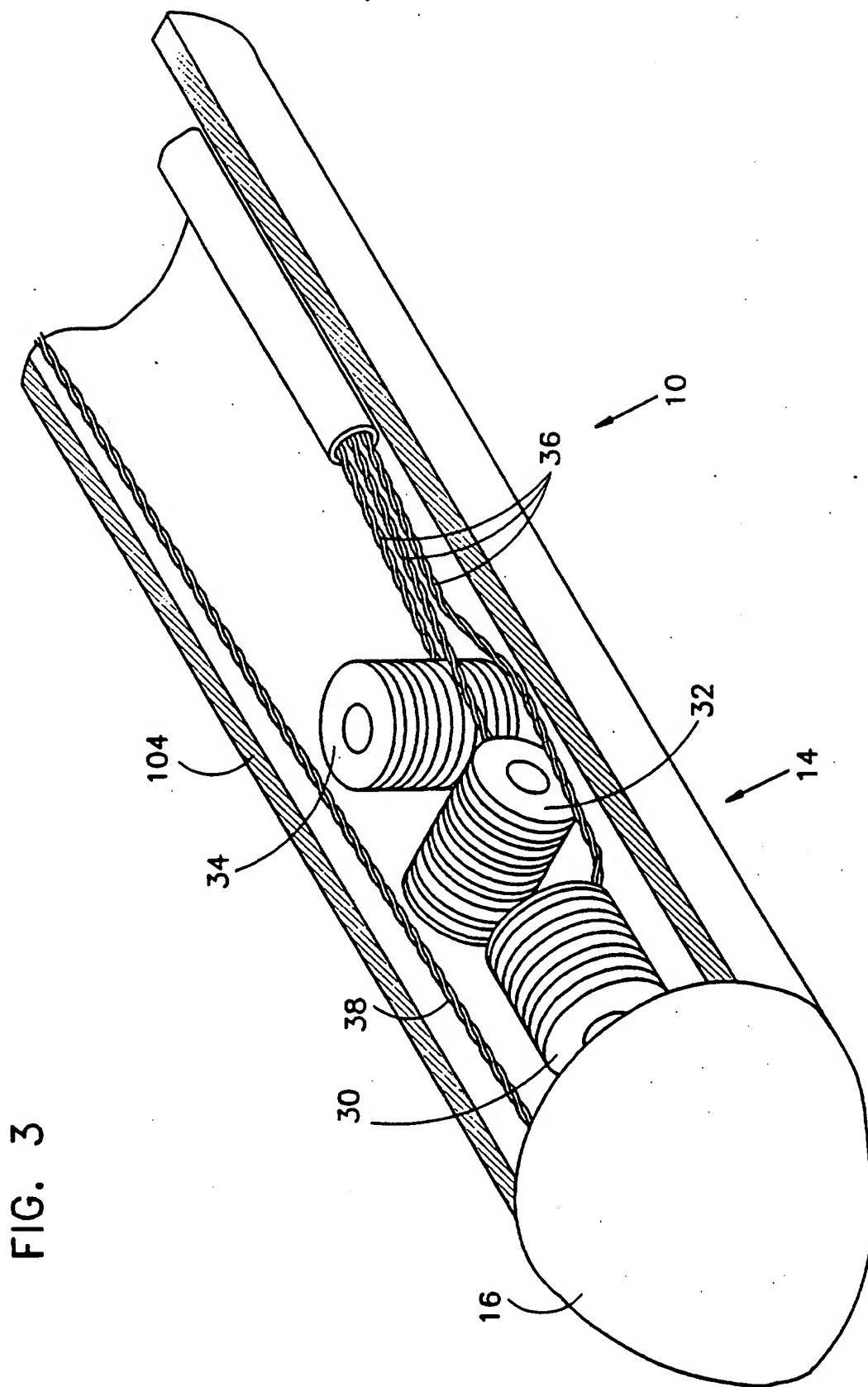
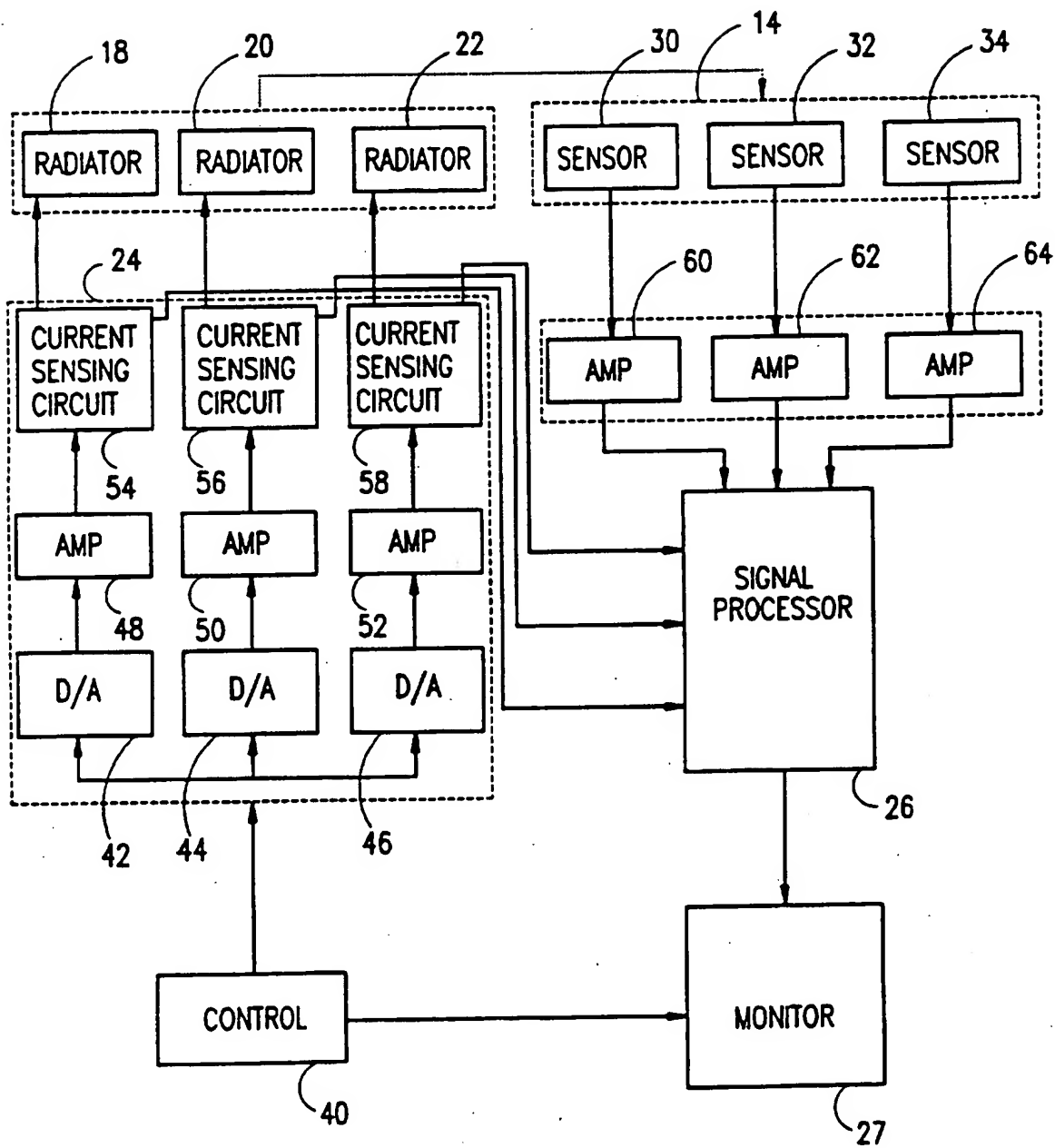


FIG. 3

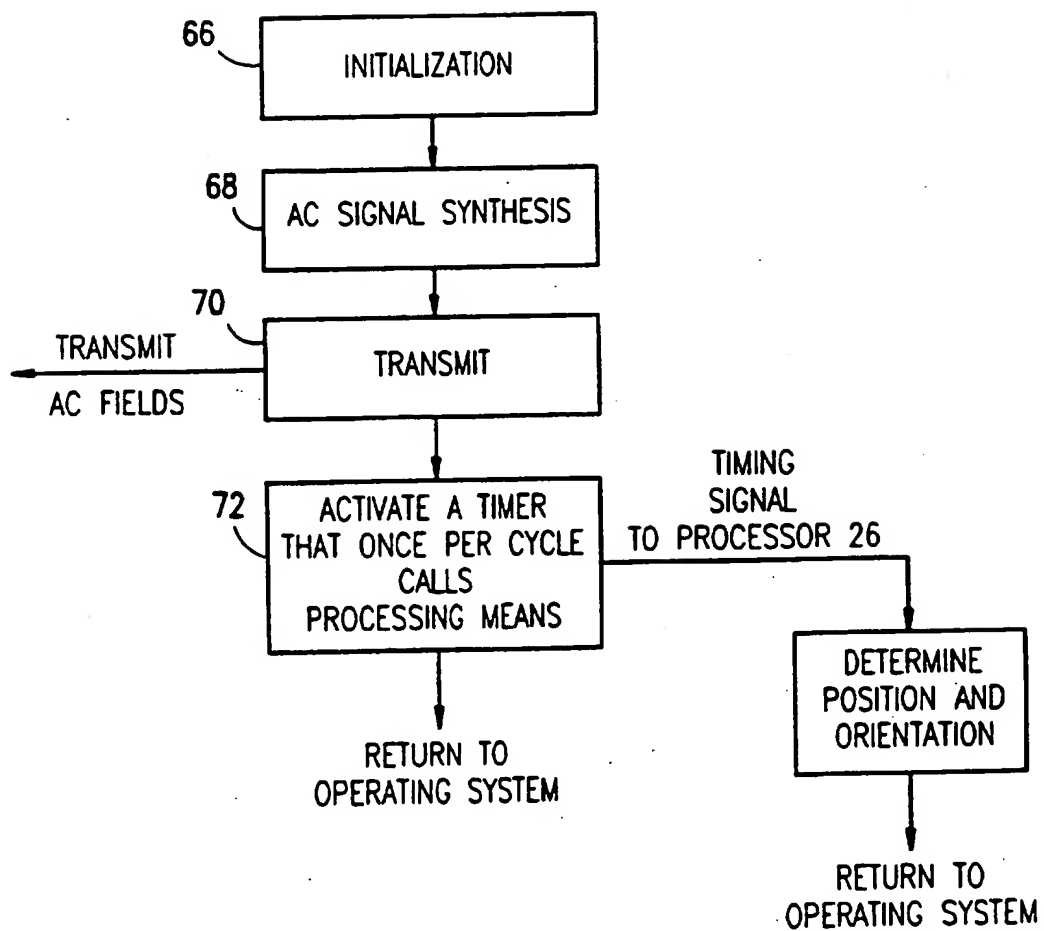
4/19

FIG. 4



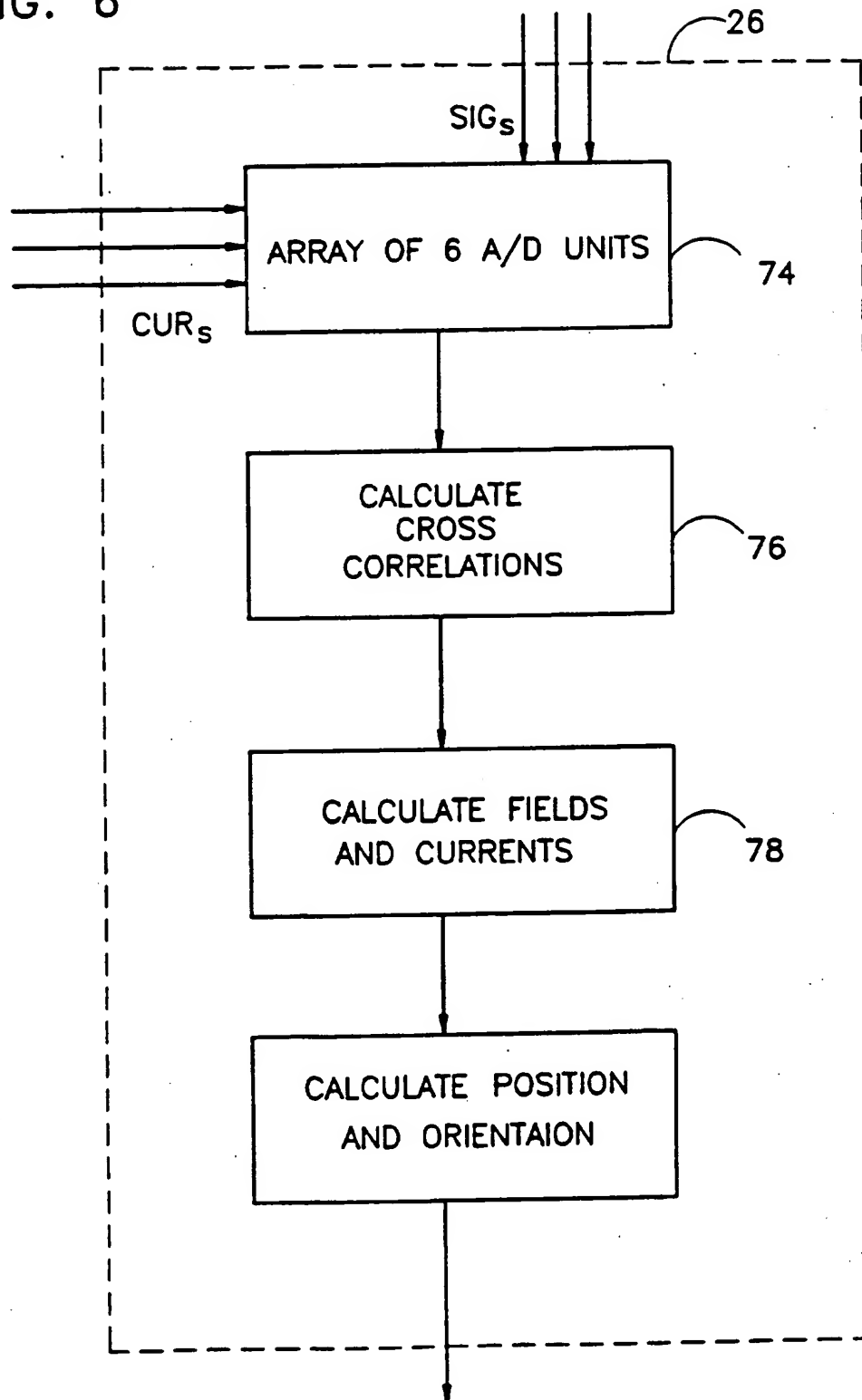
5/19

FIG. 5



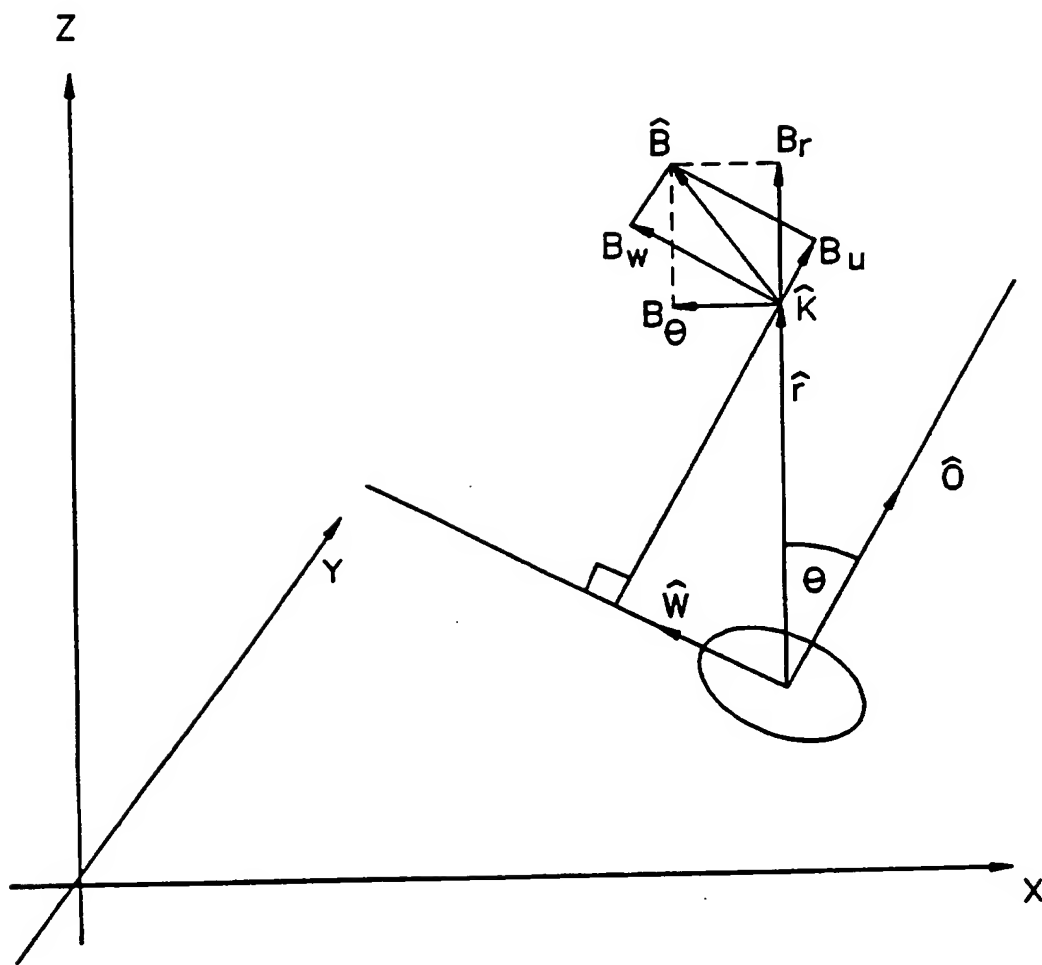
6/19

FIG. 6



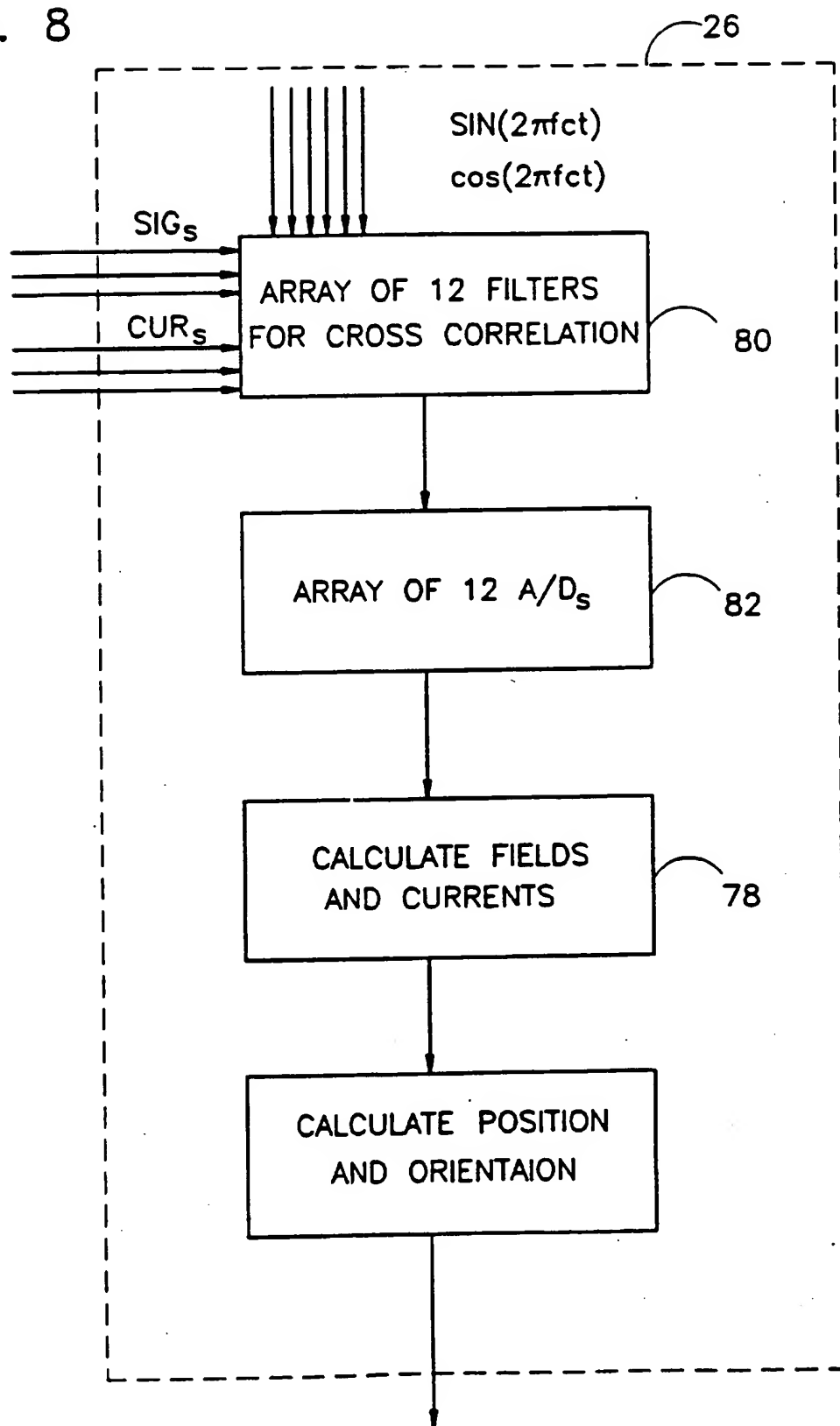
7/19

FIG. 7



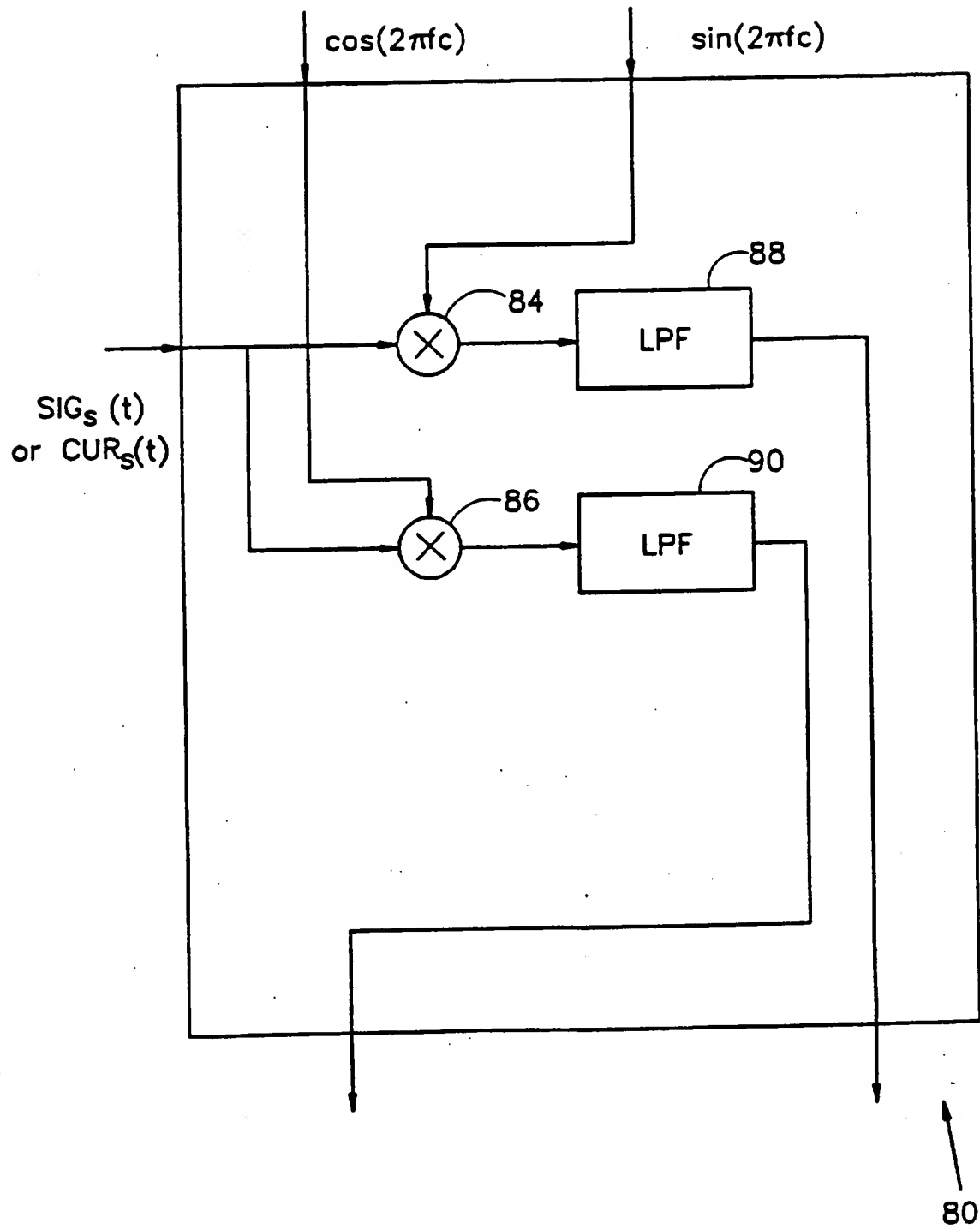
8/19

FIG. 8



9/19

FIG. 9



10/19

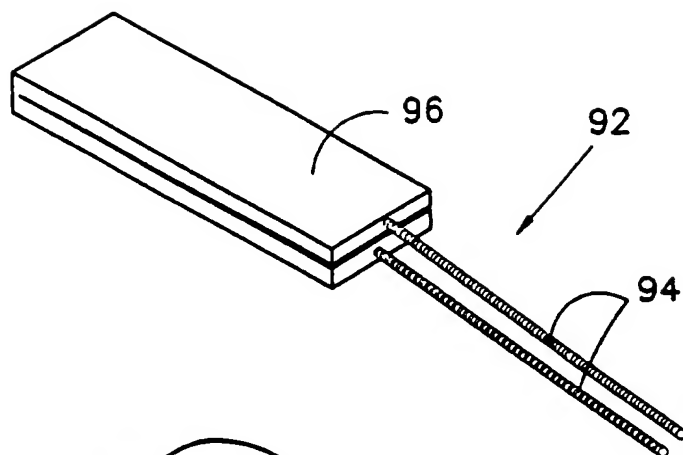


FIG. 10A

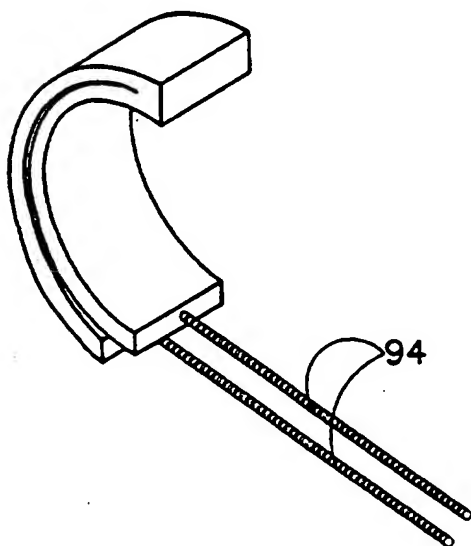


FIG. 10B

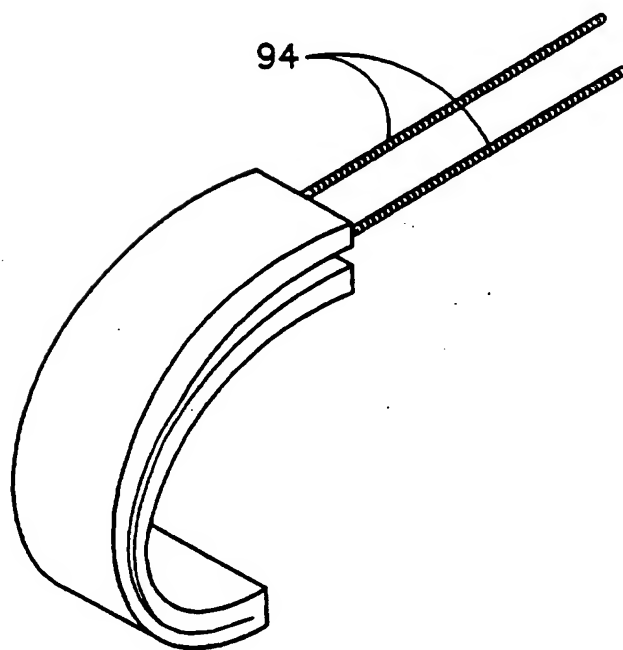
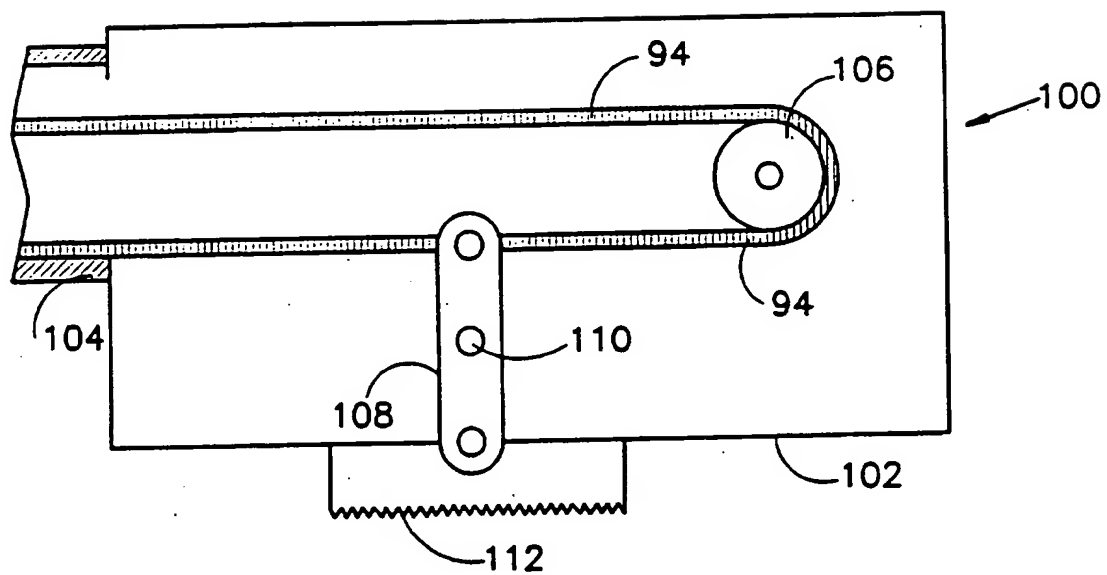


FIG. 10C

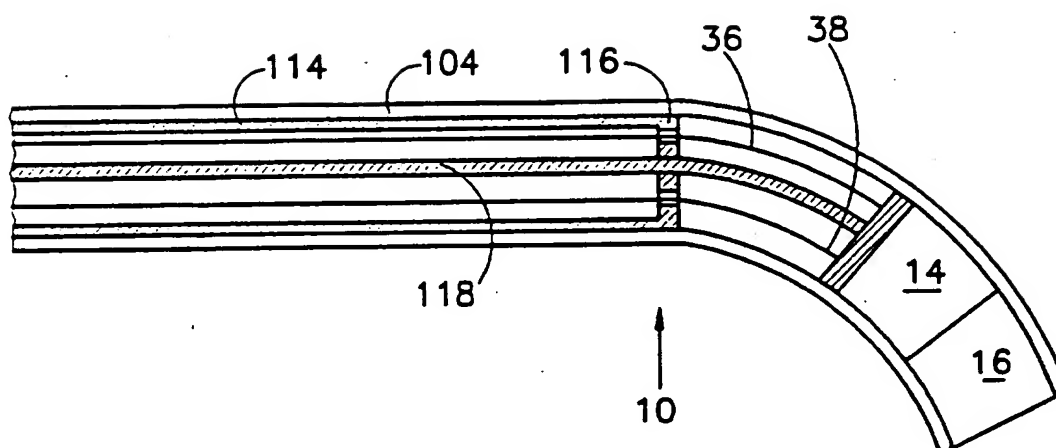
11/19

FIG. 10D



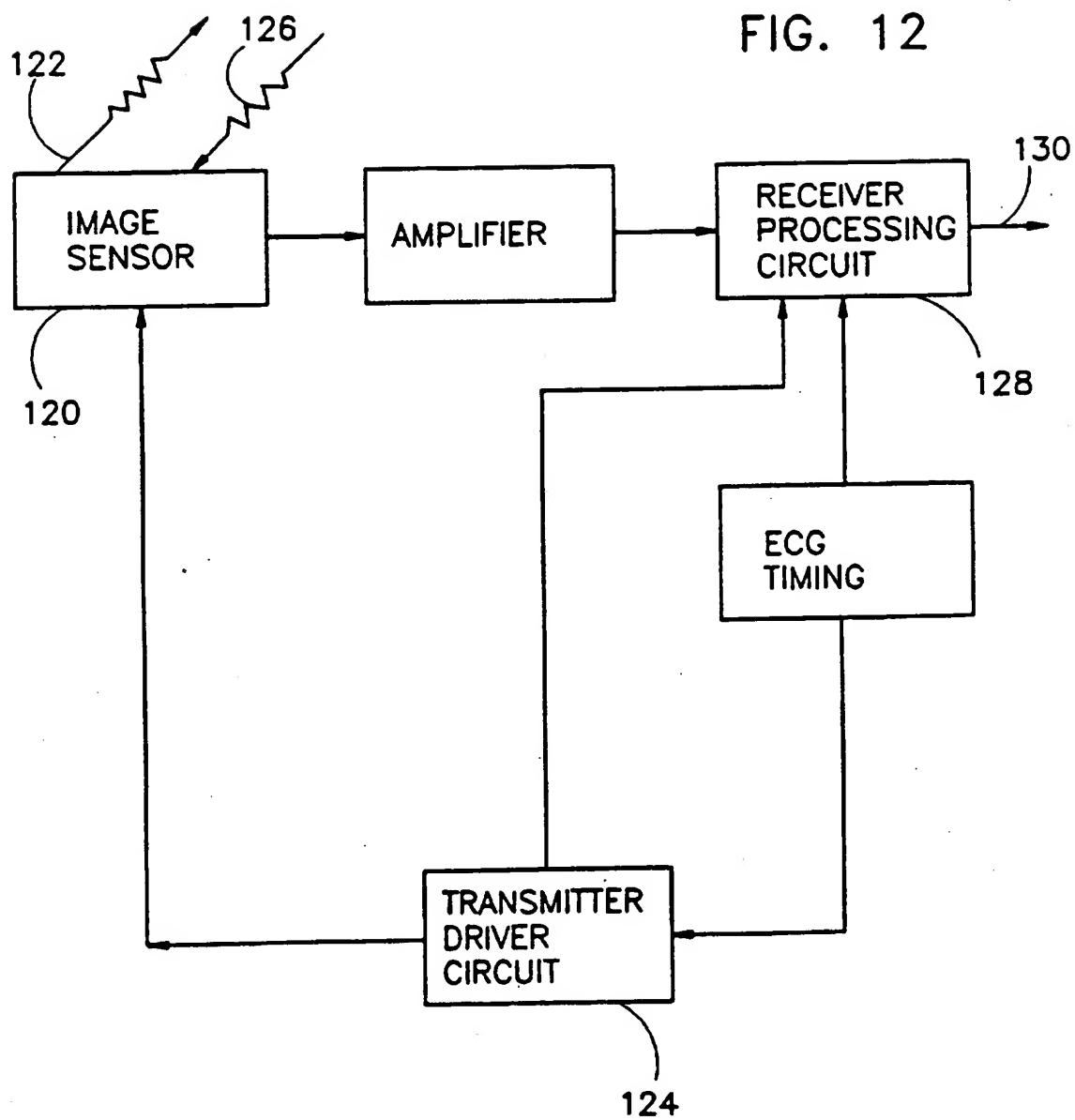
12/19

FIG. 11



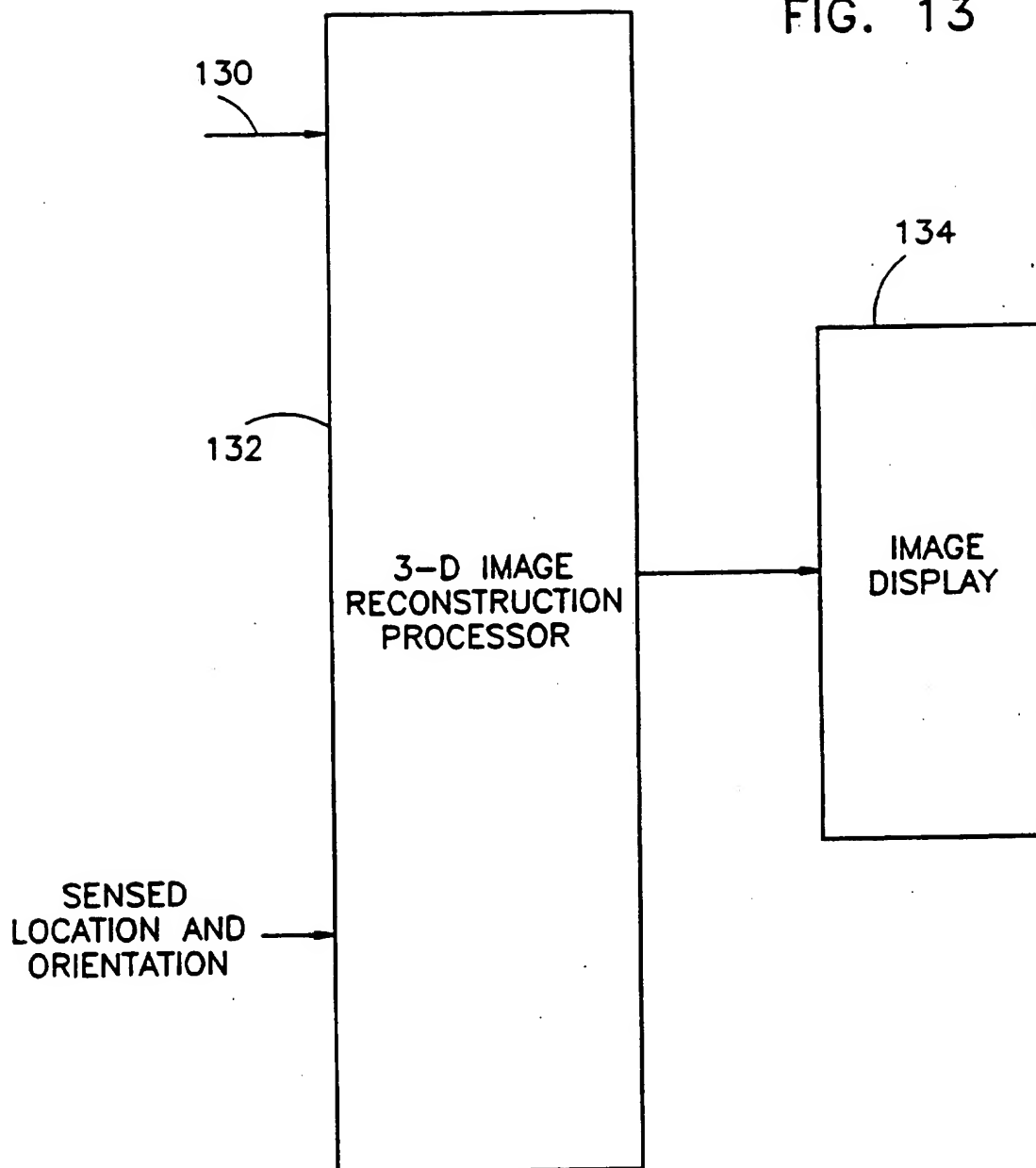
13/19

FIG. 12



14/19

FIG. 13



15/19

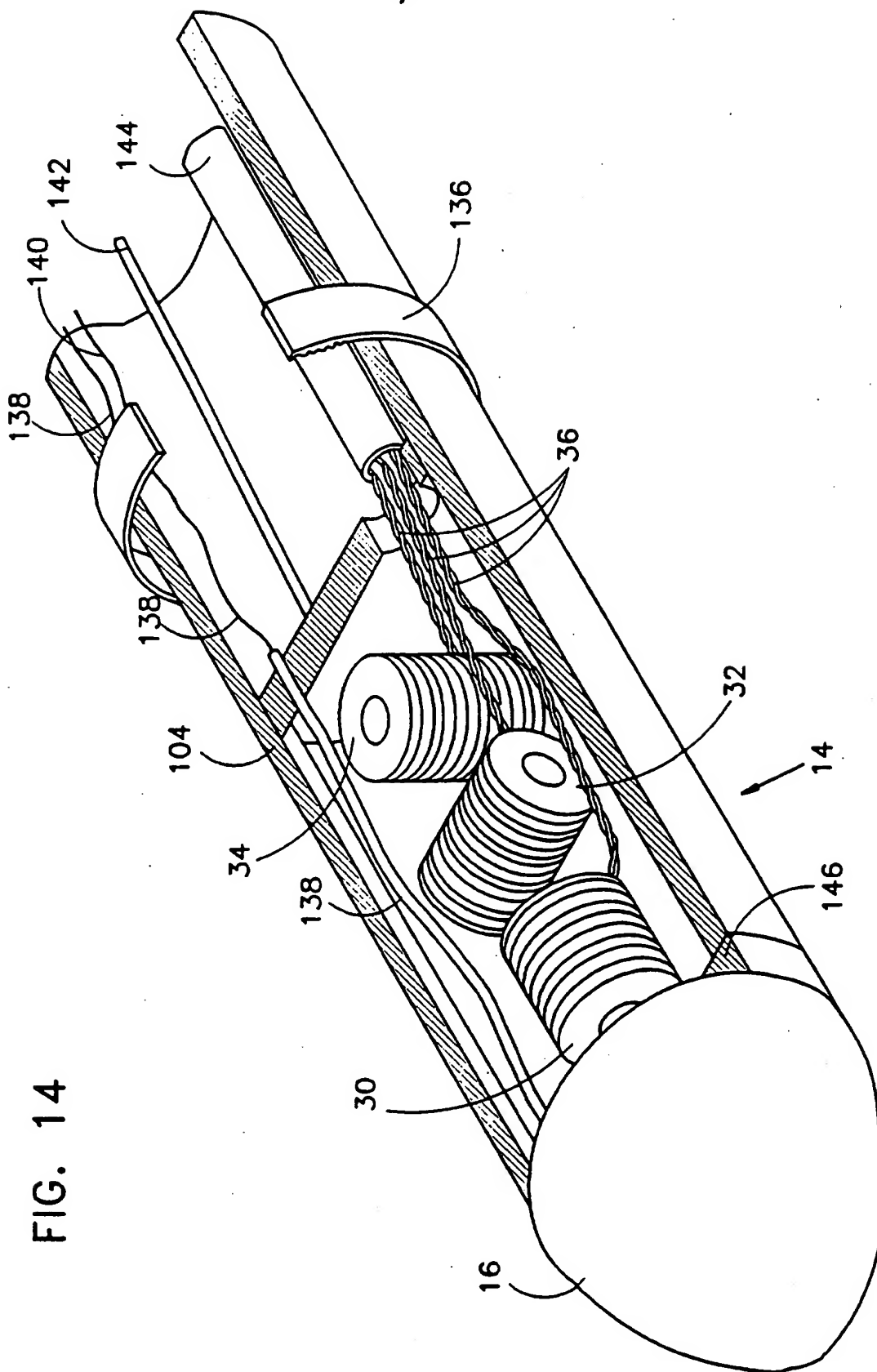


FIG. 14

16/19

FIG. 15

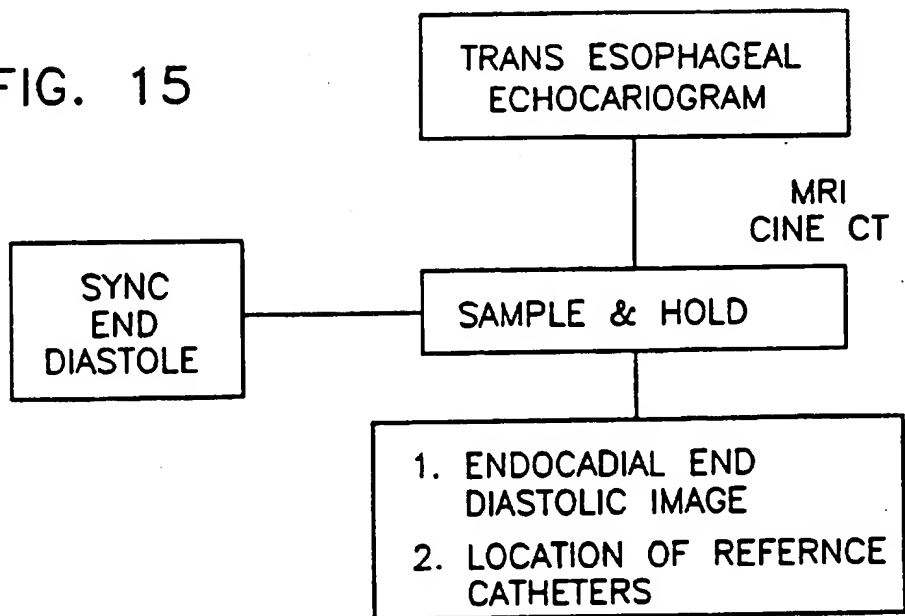
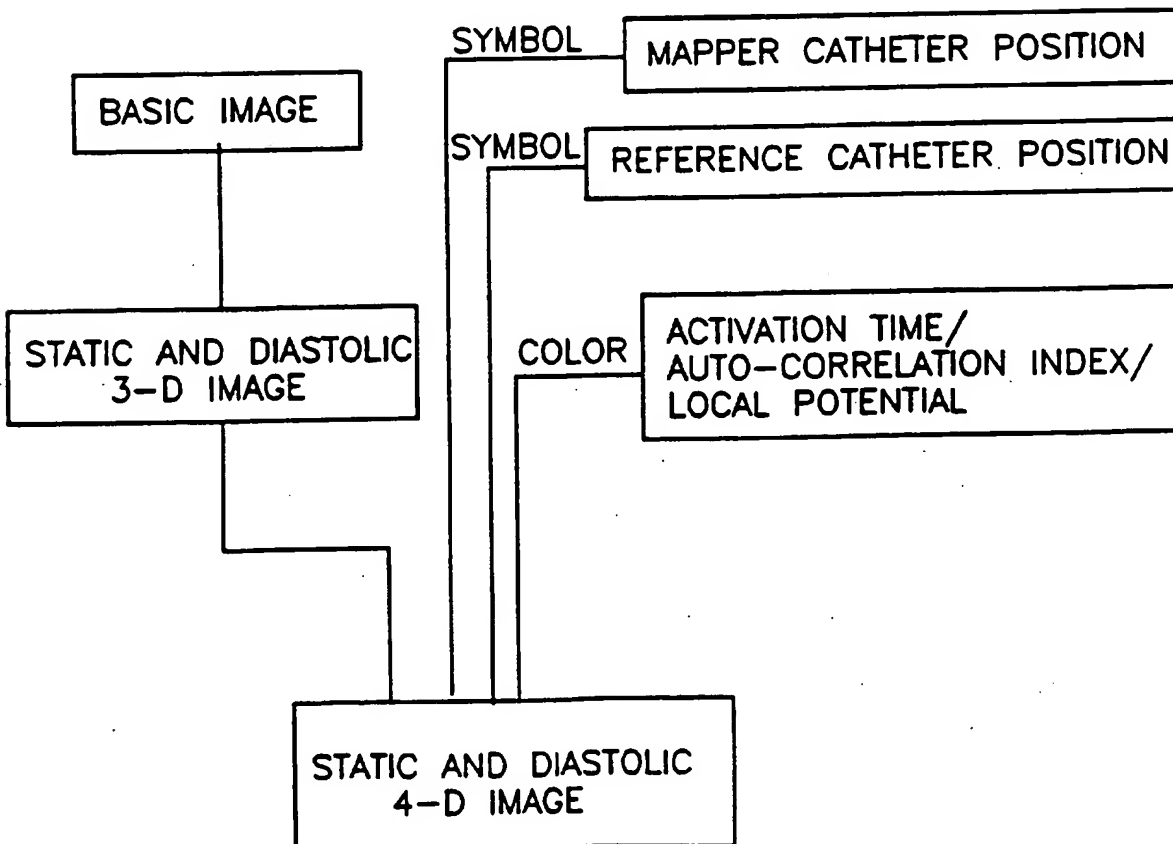


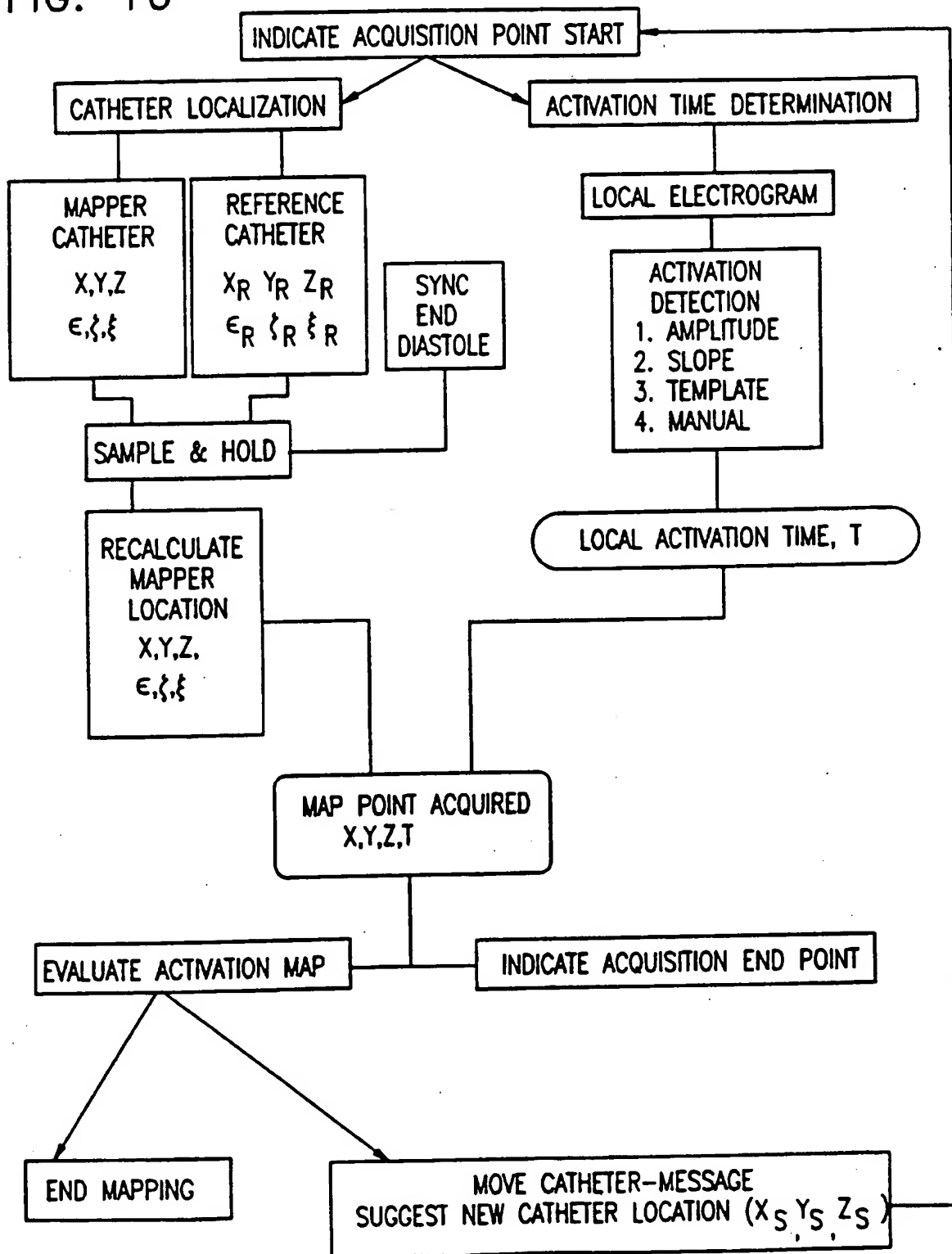
FIG. 19



17/19

FIG. 16

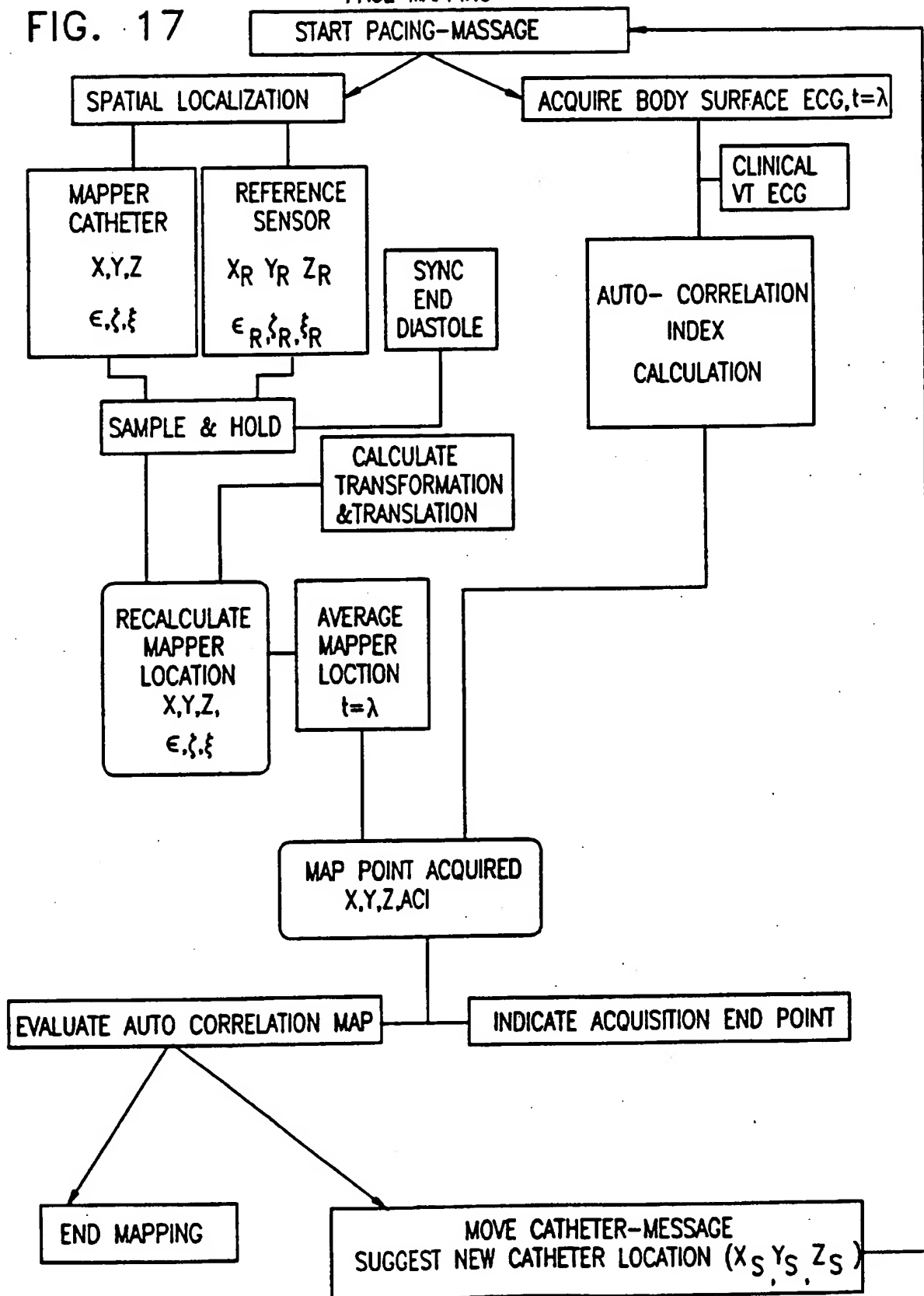
COMPUTERIZED ENDOCARDIAL ACTIVATION MAPPING



18/19

PACE MAPPING

FIG. 17



19/19

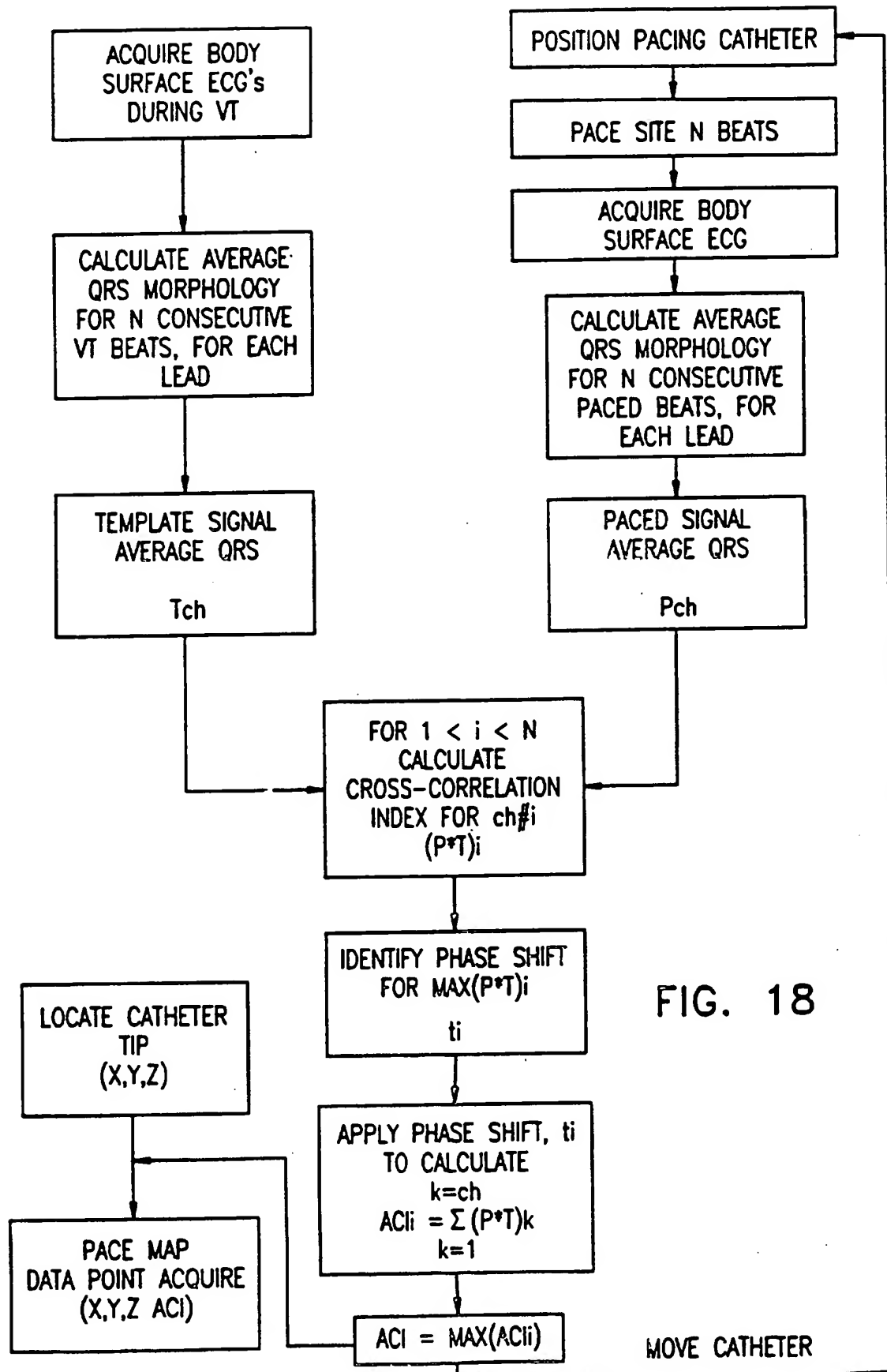


FIG. 18

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 95/01103

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B5/06 A61B8/08 A61M25/01 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,90 13259 (TOMTEC TOMOGRAPHIC) 15 November 1990	1,4, 13-17, 22-25, 34, 40-42,53
Y	see page 3, line 1 - page 4, line 13	30,38
A	see page 7, line 27 - page 10, line 14; claims; figures	2,3,18, 19,29, 31,32, 35-39, 45,46, 62-64
X	--- WO,A,92 03090 (IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY & MEDICINE) 5 March 1992 see page 1, line 20 - page 3, line 20 see page 6, line 4 - line 27; figures 1,2 --- -/--	1,4,7,8, 33,36, 40,41,53

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

6 September 1995

Date of mailing of the international search report

09.10.95

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+ 31-70) 340-3016

Authorized officer

Fontenay, P

INTERNATIONAL SEARCH REPORT

Int. onal Application No

PCT/US 95/01103

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,93 04628 (NAVION BIOMEDICAL CORPORATION) 18 March 1993 see page 4, line 1 - page 5, line 30 see page 16, line 29 - page 17, line 14; figures 1,2,5 ---	1,2,4,5, 13-15, 33,34,36
A	GB,A,2 155 736 (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY) 25 September 1985 see abstract see page 1, line 112 - line 118 see page 5, line 41 - line 46 ---	1-5,7,8, 13,14, 26,27, 33-35, 40-43
A	GB,A,2 267 035 (ARIZONA BOARD OF REGENTS) 24 November 1993 see page 7, line 23 - page 8, line 24 see page 13, line 1 - line 6 ---	16-22
X	DE,A,42 38 176 (U. NAGEL) 19 May 1994	29,31, 32,37, 39,60-64
Y	see column 1, line 3 - line 35	30,38
A	see column 2, line 35 - column 3, line 68 see column 5, line 5 - line 64; figures ---	45-48, 54-57
X	WO,A,93 07808 (INTERSPEC INC.) 29 April 1993	29,31, 32,37
A	see page 4, line 10 - page 5, line 10 see page 6, line 3 - line 17 see page 7, line 28 - page 8, line 16 ---	54,61-64
X	WO,A,93 24057 (ECHOCATH. INC.) 9 December 1993	29,31, 32,37, 39,62,64
A	see page 6, line 3 - page 7, line 10 see page 14, line 14 - page 15, line 8; figures 2,3,6,7,13 ---	45-48
X	WO,A,93 20878 (CARDIORHYTHM) 28 October 1993	60,61
A	see page 5, line 12 - page 6, line 2 see page 14, line 21 - page 15, line 19; figures 5,9-11 ---	54,57
X	WO,A,92 14506 (RAYCHEM CORPORATION) 3 September 1992	58
A	see page 11, line 31 - page 12, line 9 see page 17, line 18 - line 29; figures 1,15 ---	54,55

	-/--	

INTERNATIONAL SEARCH REPORT

Int. onal Application No

PCT/US 95/01103

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,94 03227 (STEFANADIS ET AL.) 17 February 1994 see page 2, line 11 - line 31; claim 1; figures ---	54,56
A	US,A,4 771 788 (PFIZER HOSPITAL PRODUCTS GROUP. INC) 20 September 1988 see column 4, line 49 - line 68; figures 5-8 ---	54,55,58
E	WO,A,95 02995 (BIOSENSE INC.) 2 February 1995 cited in the application see page 5, line 29 - page 8, line 32 see page 19, line 6 - page 20, line 34; figures -----	62-64

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/01103

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Subject 1: claims 1-28, 33-36, 40-44, 52
Subject 2: claims 29-32, 37-39, 45-48, 62-64
Subject 3: claims 49-51
Subject 4: claim 52
Subject 5: claims 54-57, 58, 59, 60, 61

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

Subject 2

Subject 5
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 95/01103

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9013259	15-11-90	DE-A- 3914619 DE-D- 58907254 EP-A- 0470954 JP-T- 7500506 US-A- 5295486	08-11-90 21-04-94 19-02-92 19-01-95 22-03-94
WO-A-9203090	05-03-92	AU-A- 8438991 DE-T- 4191952 GB-A, B 2263171 JP-T- 6500031 US-A- 5429132	17-03-92 15-07-93 14-07-93 06-01-94 04-07-95
WO-A-9304628	18-03-93	US-A- 5425367 AU-A- 2511592 CA-A- 2116970 EP-A- 0606253 JP-T- 7500979	20-06-95 05-04-93 18-03-93 20-07-94 02-02-95
GB-A-2155736	25-09-85	DE-A- 3506216 FR-A- 2561000	12-09-85 13-09-85
GB-A-2267035	24-11-93	US-A- 5295484 DE-A- 4316298 FR-A- 2696099 JP-A- 7000411	22-03-94 03-02-94 01-04-94 06-01-95
DE-A-4238176	19-05-94	NONE	
WO-A-9307808	29-04-93	US-A- 5255684 CA-A- 2121907 EP-A- 0615426 JP-T- 7500269	26-10-93 29-04-93 21-09-94 12-01-95
WO-A-9324057	09-12-93	US-A- 5373845 EP-A- 0641176	20-12-94 08-03-95
WO-A-9320878	28-10-93	AU-B- 4026793 US-A- 5397304	18-11-93 14-03-95
WO-A-9214506	03-09-92	US-A- 5231989	03-08-93

INTERNATIONAL SEARCH REPORT

information on patent family members

Int. onal Application No

PCT/US 95/01103

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9214506		AU-A- 1429492	15-09-92
		CA-A- 2101168	16-08-92
		EP-A- 0571531	01-12-93
		JP-T- 6505188	16-06-94
		US-A- 5345937	13-09-94

WO-A-9403227	17-02-94	NONE	

US-A-4771788	20-09-88	AU-B- 591312	30-11-89
		AU-A- 7592087	21-01-88
		CA-A- 1276717	20-11-90
		EP-A- 0253687	20-01-88
		JP-A- 63109839	14-05-88
		US-A- 4920967	01-05-90

WO-A-9502995	02-02-95	US-A- 5391199	21-02-95
		AU-B- 7372394	20-02-95
		CA-A- 2144946	02-02-95
		US-A- 5443489	22-08-95

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.